

# NovoPen® 3 Demi

Dial-A-Dose  
Insulin Delivery System  
Instructions For Use



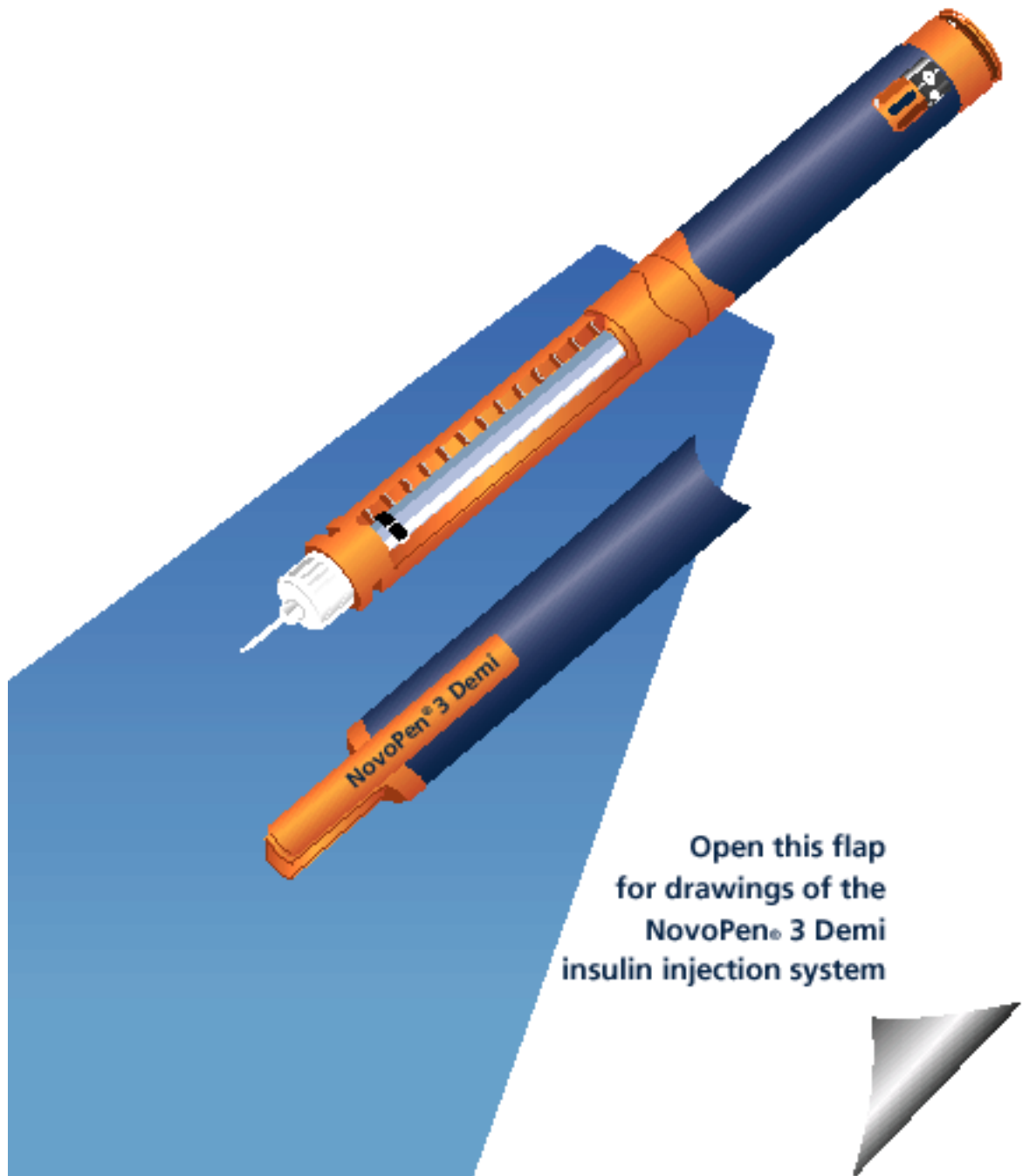
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NovoPen 3 Demi, USA

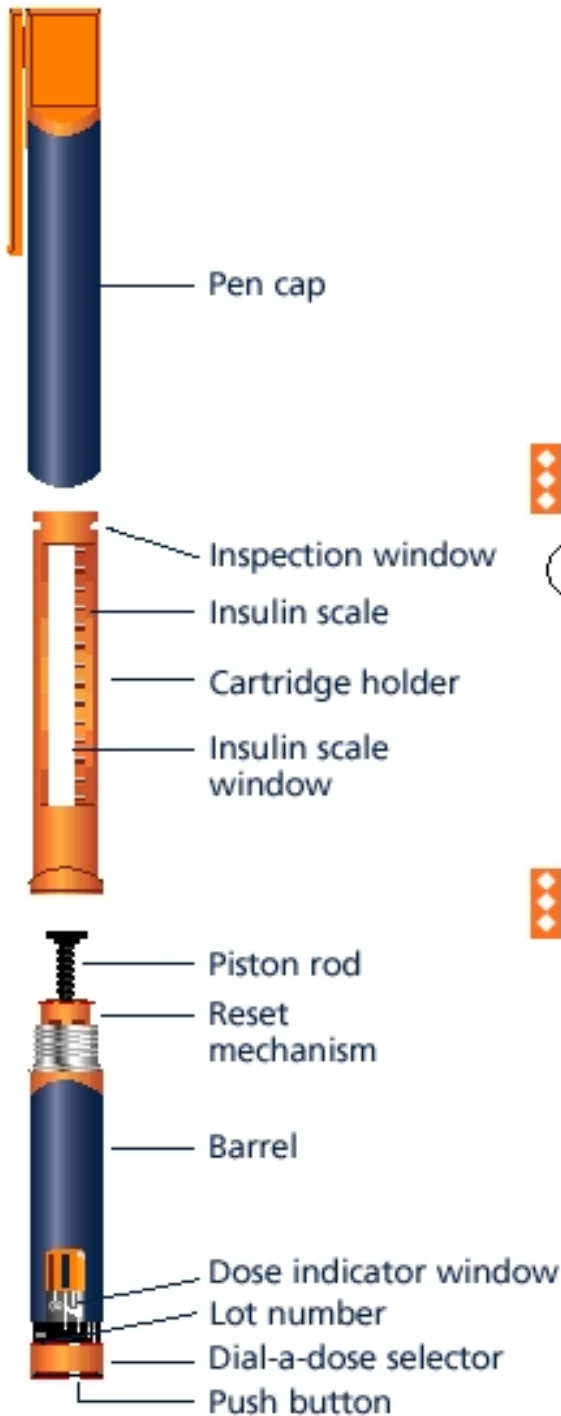
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**Novo Nordisk**

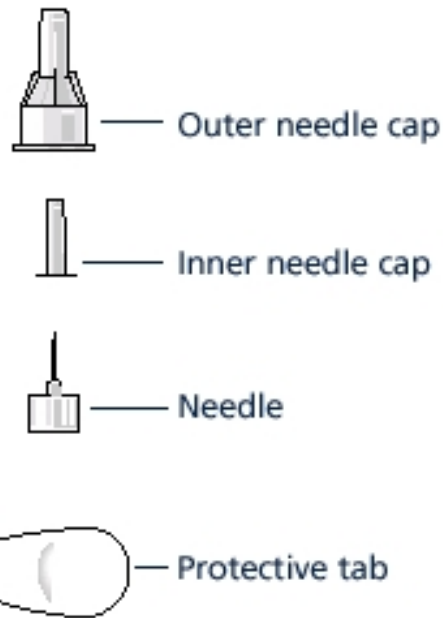


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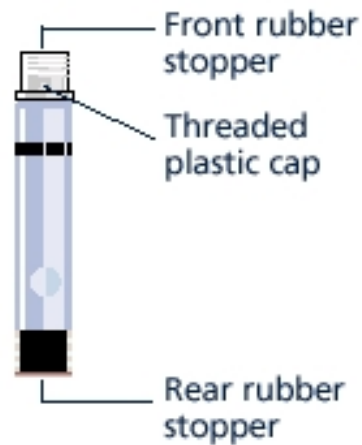
### NovoPen® 3 Demi Insulin Delivery Device



### NovoFine® Disposable Needle



### PenFill® Cartridge (3 mL)



Need Help?  
Call 1-800-727-6500

# 4 **NovoPen<sup>®</sup> 3 Demi Instruction Manual**

## 5 6 **Dial-A-Dose Insulin Delivery System**

### 7 8 **INTRODUCTION**

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12  
13 NovoPen<sup>®</sup>3 Demi delivers a minimum dose of 1 unit to a maximum dose of 35  
14 units of insulin in half unit steps. A raised circle on the push button makes it easy  
15 for you to know your NovoPen 3 Demi from the ordinary NovoPen 3. This booklet  
16 includes everything you need to know about using the NovoPen 3 Demi. Please  
17 read it carefully before using your NovoPen 3 Demi for the first time.

18  
19 The NovoPen 3 Demi is designed for use with:

- 20 ■ PenFill<sup>®</sup> 3 mL cartridges.
- 21 ■ NovoFine<sup>®</sup> disposable needles.

22 **NovoFine disposable needles are for single-use only.**

23 You will also need alcohol swabs.

24  
25 If you have any questions about your NovoPen 3 Demi insulin delivery system,  
26 please call Novo Nordisk Pharmaceuticals, Inc. at 1-800-727-6500.

27  
28 **Please complete and return the NovoPen 3 Demi warranty card.**

29  
30  
31  
32 See **Important Things to Know** and **Important Notes** on pages 33-35.

33  
34

35 **HOW TO USE THIS BOOKLET**

36

37 **This booklet gives you step-by-step instructions for using the NovoPen 3**  
38 **Demi.**

39

40 Begin by reviewing the drawing layout of the parts of the NovoPen 3 Demi,  
41 PenFill 3 mL cartridge, and NovoFine disposable needle. The inside front cover  
42 opens out so you have a handy reference while you read the rest of the booklet.

43

44 Most pages contain a drawing on the right with numbered instructions to the left  
45 of the drawing.

46 **Important additional information is given below the drawing.**

47

48 We suggest that you **read the text and look at the drawing** to make sure that  
49 you understand each step thoroughly.

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116 **SECTION 1**            **Preparing the NovoPen 3 Demi**  
117

118 **Remove the device cap:**

- 119     1. Remove the NovoPen 3 Demi from the case.  
120     2. Gently twist the pen cap until the cap separates from the barrel.  
121     3. Pull the pen cap straight up to remove it.  
122



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Call 1-800-727-6500

123  
124  
125 **If you use more than one insulin product (such as Novolin® R, Novolin® N,**  
126 **Novolin® 70/30, or NovoLog®), use a separate insulin delivery device for each**  
127 **product.**

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129 **SECTION 1 (cont.)**

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131 **Separate the cartridge holder from the barrel:**

132

- 133 4. Unscrew and remove the cartridge holder from the barrel.

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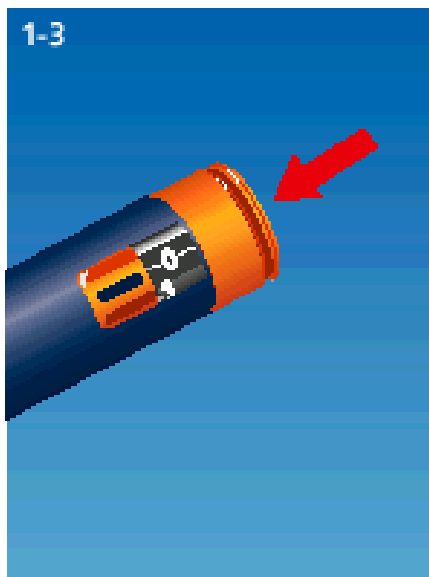
136

137 **Make sure the dose indicator window shows zero:**

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- 139 5. Press the push button all the way in until zero (0) appears in the window.  
140 The zero should be lined up with the stripe below the dose indicator  
141 window.

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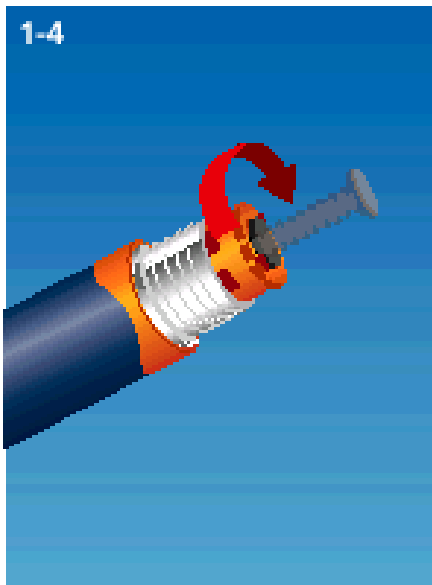
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**SECTION 1 (cont.)**

The end of the piston rod should be flat against the end of the reset mechanism prior to inserting each new PenFill 3 mL cartridge. It should not be sticking out.

**If the piston rod is sticking out:**

Turn the end of the reset mechanism in a clockwise direction until it is no longer sticking out. Never push the piston rod back in.



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Call 1-800-727-6500

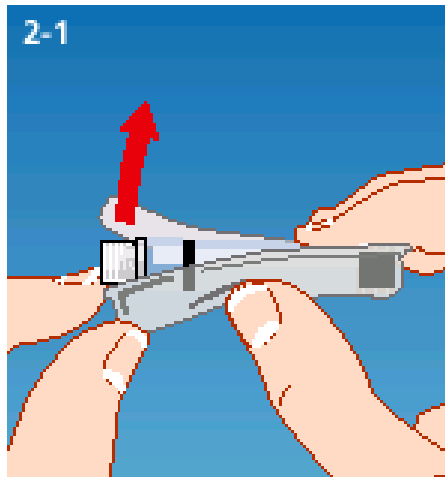
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You should never reset the piston rod until it is time to remove the used PenFill 3 mL cartridge and insert a new one.

If the reset mechanism locks, it is usually due to improper technique. Gently turn the mechanism side to side until it unlocks. Then call our toll free number (1-800-727-6500) so that we may go over your technique with you.

167 **SECTION 2                    Inserting the PenFill 3 mL Cartridge**  
168

- 169 1. To remove the PenFill cartridge from its wrapper, push the cartridge  
170 through the foil side of the packaging. Always make sure that the PenFill  
171 cartridge you use contains the correct type of insulin (such as Novolin R,  
172 Novolin N, Novolin 70/30, or NovoLog). If you are treated with more than  
173 one type of insulin in PenFill cartridges, you should use a separate insulin  
174 delivery device for each type of insulin. Before use, check that the PenFill  
175 cartridge is full and intact. If not, do not use it.  
176



- 177  
178  
179 2. In the PenFill Information For The Patient leaflet, you will find instructions  
180 on how to prepare the insulin if the PenFill contains a suspension insulin  
181 (white and cloudy) such as Novolin N or Novolin 70/30.  
182  
183

184 Each PenFill 3 mL cartridge contains a total of 300 units of insulin. Make sure  
185 you are using the correct type of insulin. On the glass part of the cartridge is the  
186 name of the insulin.

187  
188 Each PenFill cartridge is for single-person use only. DO NOT share the same  
189 cartridge with anyone even if you attach a new disposable needle for each  
190 injection. Sharing the cartridge can spread disease.

191 **Use only a new PenFill 3 mL cartridge when loading the NovoPen 3 Demi.**

192 **Never load a partially filled cartridge.**

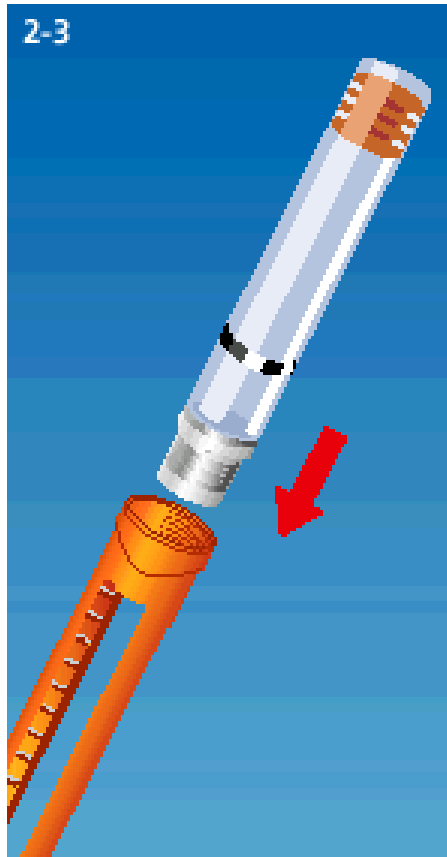
193 **Never try to refill a used PenFill 3 mL cartridge.**  
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**SECTION 2 (cont.)**

**Insert the PenFill cartridge:**

2. Hold the cartridge holder so the wider opening is up.
3. Drop the PenFill cartridge into the cartridge holder, plastic cap first.



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A threaded plastic cap surrounds the end of the PenFill® cartridge, like the cap on a bottle. In the center is the front rubber stopper.

The rear rubber stopper is at the other end of the PenFill cartridge.

212 **SECTION 2 (cont.)**

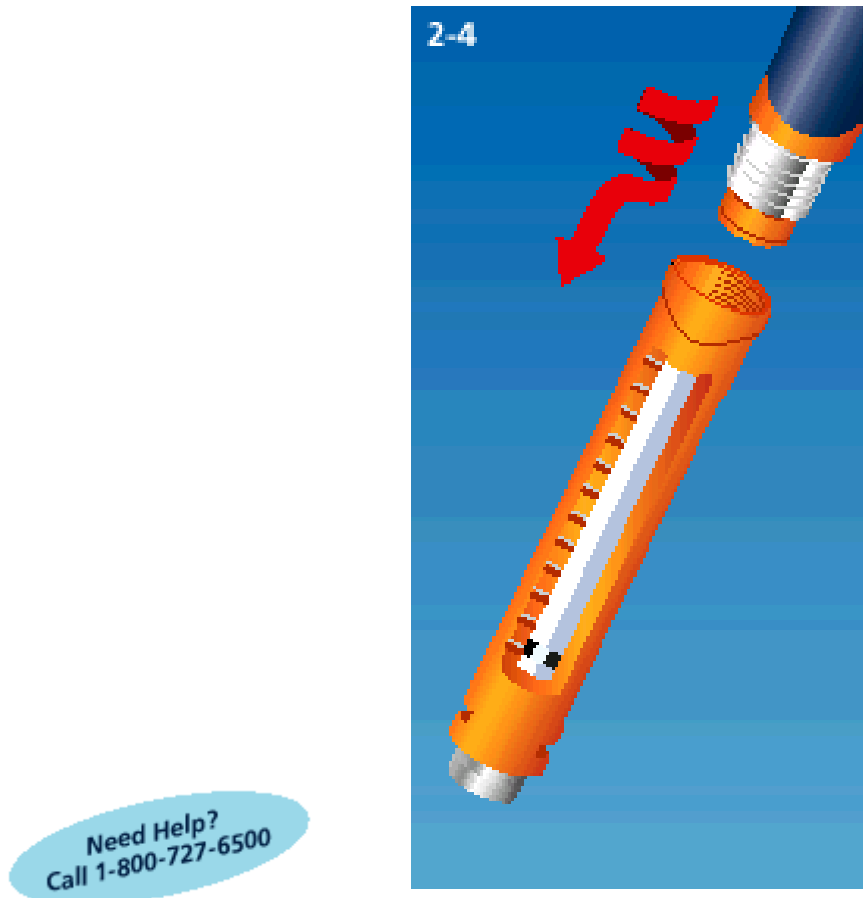
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214 **Re-attach the cartridge holder:**

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216 4. Screw the barrel into the cartridge holder completely until it is tight.

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222 You can see the cartridge in the insulin scale window. The cartridge holder has a  
223 scale with marks showing about how much insulin is left in the PenFill cartridge.

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227 **SECTION 3 Attaching the NovoFine® Disposable Needle**  
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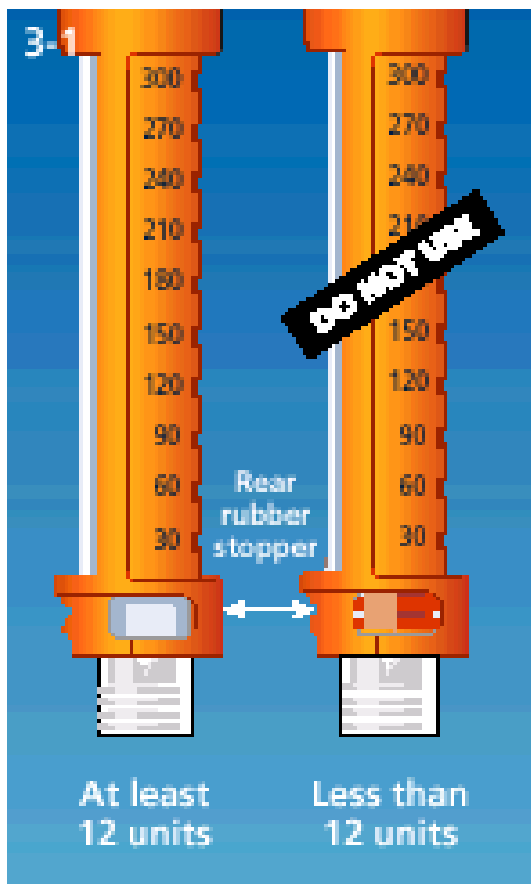
229 At the end of the cartridge holder are two inspection windows. You can see the  
230 cartridge through these windows.  
231

232 **If you use a suspension insulin (white and cloudy) such as Novolin® N or**  
233 **Novolin® 70/30, use the windows to check if there is enough insulin left for**  
234 **proper mixing.** (see below)  
235

236 **Check the amount of insulin remaining:**

- 237 ■ If the rear rubber stopper cannot be seen in the inspection window, you have  
238 enough insulin for mixing left in the cartridge.
- 239 ■ If the rear rubber stopper can be seen in the inspection window, you do not  
240 have enough insulin left in the cartridge and must insert a new PenFill 3 mL  
241 cartridge.  
242

243 See Section 7 for instructions on removing a PenFill cartridge and Section 2 for  
244 inserting a new one.  
245





249 **SECTION 3 (cont.)**

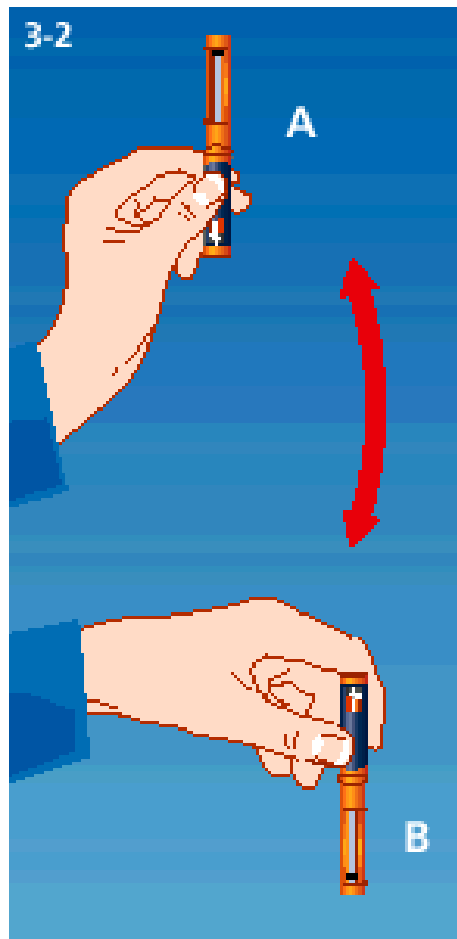
250

251 **For users of suspension insulin (white and cloudy) such as Novolin N or**  
252 **Novolin 70/30:**

253

254 **Always remix the insulin before each injection.**

255 To remix the insulin, turn the NovoPen 3 Demi up and down between positions **A**  
256 and **B** 10 times or until the insulin looks uniformly white and cloud  
257



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Call 1-800-727-6500

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**SECTION 3 (cont.)**

1. Wipe the front rubber stopper with an alcohol swab.



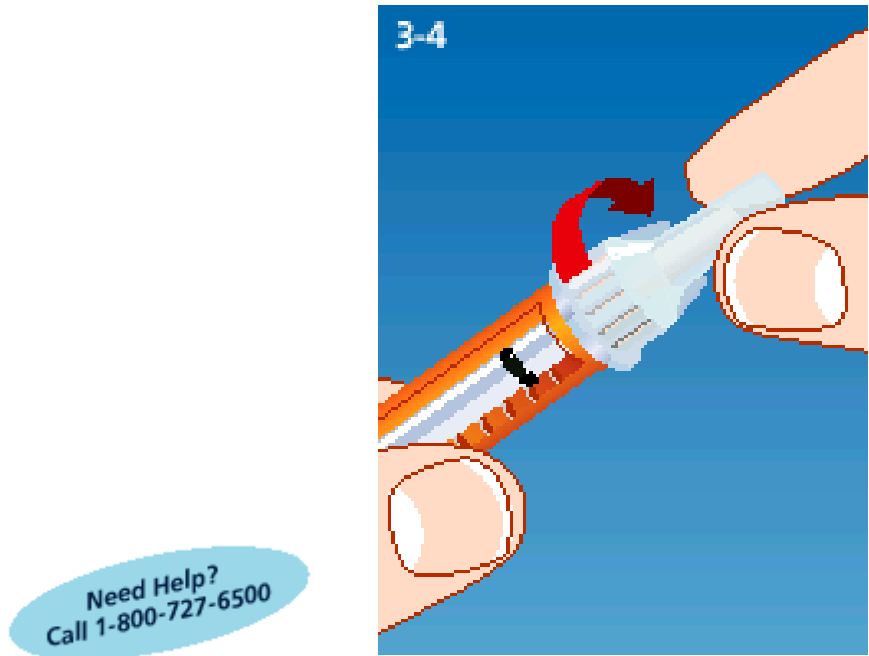
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You must wipe the front rubber stopper with an alcohol swab before each injection, even if you are using the same PenFill cartridge.

272 **SECTION 3 (cont.)**

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2. Remove the protective tab from the NovoFine disposable needle.
3. Screw the NovoFine disposable needle firmly onto the PenFill 3 mL cartridge until it is tight.



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Never place a NovoFine disposable needle on your NovoPen 3 Demi until you are ready to do an air shot and give an injection. If the NovoFine needle is left on, some liquid may leak out of the PenFill cartridge. This may cause a change in the strength of the suspension insulin such as Novolin N or Novolin 70/30.

286

287 **SECTION 4                    Doing an Air Shot**

288

289 The PenFill cartridge may contain an air bubble, and small amounts of air may  
290 collect in the needle and PenFill cartridge when you use them. To avoid injecting  
291 air and to ensure proper dosing, you must perform an air shot before each  
292 injection.

293

294 **Before doing the air shot, the dose indicator window must show zero (0).**

295

296 If you use a suspension insulin, such as Novolin N or Novolin 70/30 and have  
297 used the PenFill cartridge for previous injections, make sure there is enough  
298 insulin left in the PenFill cartridge to properly mix the insulin (see page 12). If  
299 there is enough insulin left in the PenFill cartridge, see the next page for  
300 instructions.

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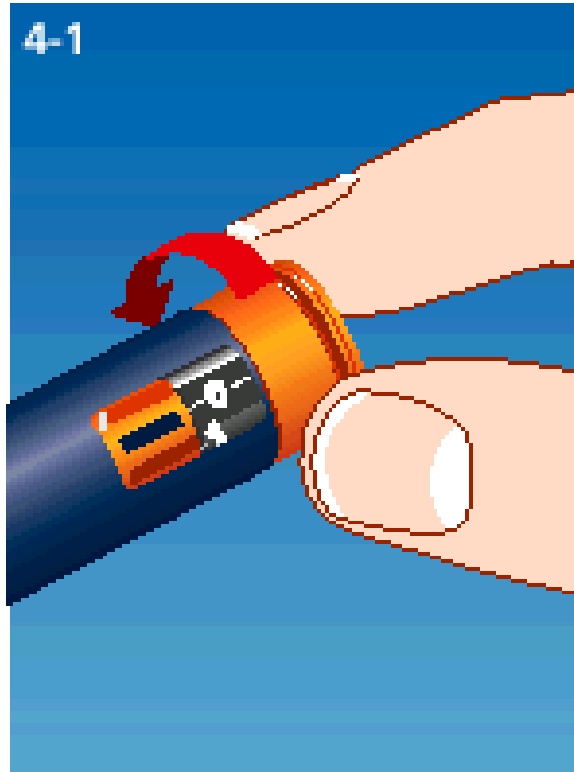
303 **SECTION 4 (cont.)**

304

305 **Set the NovoPen 3 Demi for the air shot:**

306

- 307 1. Turn the dial-a-dose selector to 2 units. Full units are shown as numbers.  
308 Half units are shown as long lines between the numbers.  
309



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310

311

312 **If you dial more than 2 units, DO NOT turn the dial back to zero (0).** If you  
313 do, the extra insulin will squirt out of the needle. You may complete the air shot  
314 with the number of units you have dialed or refer to Section 5 on page 21 for  
315 instructions on how to reset the dose to zero.

316

317 **SECTION 4 (cont.)**

318

319 **Uncap the NovoFine needle:**

320

321 2. Pull off the outer needle cap and set aside.

322 3. Pull off the inner needle cap and discard.

323

324 Do not use the needle if it is bent or damaged.

325



326

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328 4. Hold the NovoPen 3 Demi with the NovoFine needle pointing up.

329 5. Tap the cartridge holder with your finger a few times to raise any air  
330 bubbles that may be present to the top of the cartridge.

331



332

333

334 **SECTION 4 (cont.)**

335

336 **Do the air shot:**

337

338 6. Press the push button all the way in. A drop of insulin should appear at the  
339 needle tip.

340

341 **If no insulin appears, repeat the following steps, until a drop of insulin**  
342 **appears:**

343

344 a. Make sure the NovoFine needle is securely attached.

345 b. Dial 2 units.

346 c. Tap the cartridge holder with your finger.

347 d. Press the push button all the way in.

348

349 There may still be some small air bubble(s) in the PenFill cartridge after this, but  
350 they will not affect your dose and they will not be injected.

351



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When you press the push button, the piston rod presses against the rear rubber stopper. This moves the rear rubber stopper and pushes the correct amount of insulin up through the needle.



358 **SECTION 5 Giving the Injection**

359

360 **Be sure to do an air shot before giving each injection (see pages 16-19).**

361

**Select the dose:**

362

363

1. Check that the dial-a-dose selector is set to zero. If not, follow the instructions on the next page. Turn the dial-a-dose selector until you see the correct number of units in the dose indicator window. Full units are shown as numbers. Half units are shown as long lines between the numbers.

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**DO NOT use the clicking sound as a guide for selecting your dose.**

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The NovoPen 3 Demi can deliver insulin in half unit steps from a minimum dose of 1 unit to a maximum dose of 35 units.

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**If you dial more than your dose, DO NOT turn the dial back to zero (0).** If you do, the extra insulin will squirt out of the needle. For instructions on how to reset the dose to zero (0) so you can start again, see the next page.

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382 **SECTION 5 (cont.)**

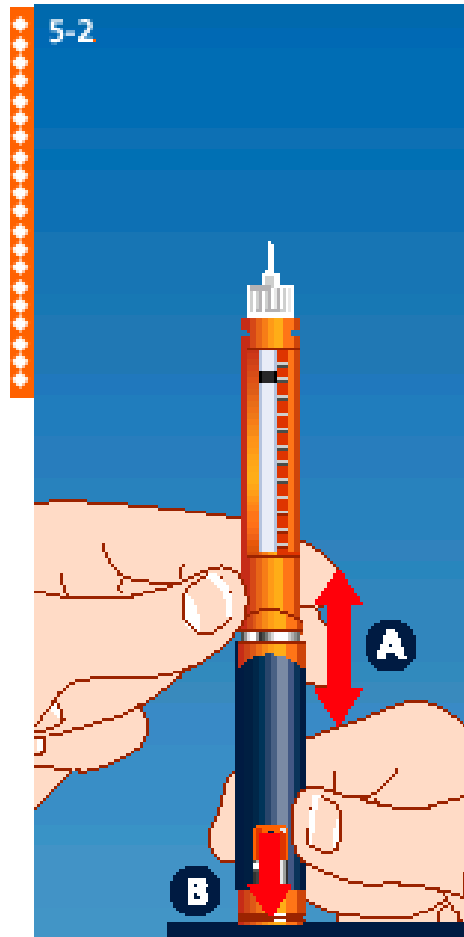
383

384 If you dial a larger dose than you need, pull the barrel and the cartridge holder  
385 apart, as shown in the drawing **A**. While holding them apart, gently press the  
386 push button against a hard surface and release your grip **B**. Your dose indicator  
387 window should be back to zero (0).

388

389 You can now dial the correct number of units.

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394 **SECTION 5 (cont.)**

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396 **Giving the injection:**

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2. After the air shot is done and you have chosen the correct number of units, insert the NovoFine needle in the correct injection site on your body. (Use the injection technique recommended by your health care professional). If you use a suspension insulin such as Novolin N or Novolin 70/30, mix the insulin (see page 13, Section 3) and make sure the insulin looks uniformly white and cloudy before you inject.
3. Press the push button **as far as it will go** to deliver the insulin. Do not force it.

To ensure that all the insulin is injected, keep the NovoFine needle in the skin for several seconds after the injection with your thumb on the push button. Keep the push button fully depressed until after the NovoFine needle has been withdrawn.

**Important: Never turn the dial-a-dose selector to inject the insulin.**



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When you get near the end of a PenFill cartridge, you may need to give yourself two injections to receive your full dose. Check the dose indicator window after

418 giving an injection. If zero does not appear in the dose indicator window, you did  
419 not receive your full dose. See the next page for instructions on how to get the  
420 remaining part of your dose.  
421 22

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423

**SECTION 5 (cont.)**

424

425

**4. Check the dose indicator window to make sure it shows zero (0). If zero does not appear, you did not receive the full dose.**

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If the dose indicator window does not show zero, there were not enough units of insulin in the PenFill cartridge for you to receive the full dose. The dose indicator window shows the number of units that you did not receive.

429

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For example, if you dial **25** units and there are only **20** units left in the PenFill cartridge, after the injection the number in the dose indicator window will be **5** ( $25-20 = 5$ ). If this happens, proceed with the following steps to get the remaining part of your dose:

433

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a. Note the number of units in the dose indicator window.

439

b. Remove the NovoFine needle (see Section 6).

440

c. Remove the empty PenFill 3 mL cartridge (see Section 7).

441

d. Insert a new PenFill 3 mL cartridge (see Section 2).

442

e. Attach a NovoFine needle (see Section 3).

443

f. Do an air shot (see Section 4).

444

g. Dial the number of units noted in step a.

445

h. Give the injection.

446

447



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451 **SECTION 6 Removing the NovoFine Disposable Needle**

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453 **Remove the NovoFine disposable needle:**

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455 1. After the injection, remove the needle without replacing the cap.

456

457 2. Hold the cartridge holder firmly while you unscrew the NovoFine  
458 disposable needle.

459

460 3. Place the NovoFine disposable needle in a puncture-resistant disposable  
461 container.

462

463 Health care professionals, relatives, and other caregivers should also follow the  
464 above instructions to eliminate the risk of unintended needle penetration.

465

466

467

468 **The NovoFine disposable needle must be removed immediately after each**  
469 **injection without replacing the cap.** If the NovoFine disposable needle is not  
470 removed, some liquid may leak out of the PenFill cartridge. This may cause a  
471 change in the strength of suspension insulins (white and cloudy) such as Novolin  
472 N or Novolin 70/30.

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474 For information on how to throw away needle containers properly, contact your  
475 local trash company.

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477 **SECTION 6 (cont.)**

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479 **Replace the pen cap:**

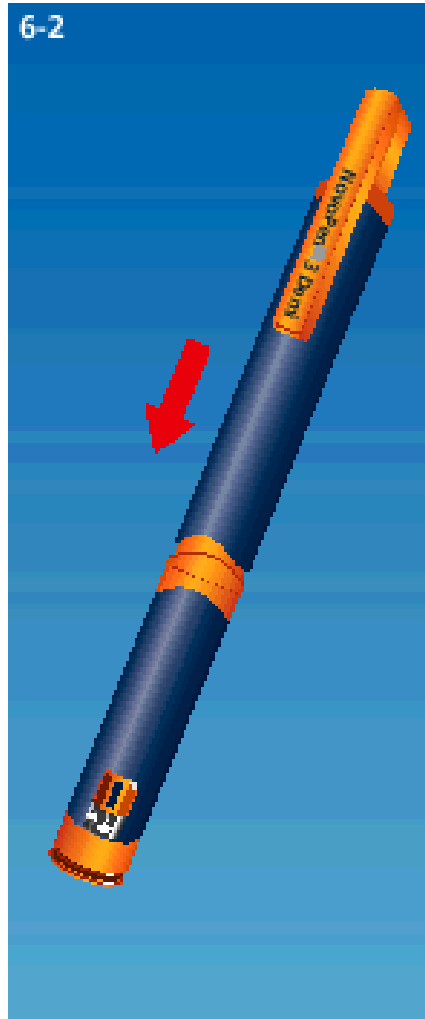
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481 4. After you remove the disposable needle, hold the pen cap so that the clip  
482 is lined up with the dose indicator window.

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484 5. **Gently slide** the pen cap onto the barrel.

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Call 1-800-727-6500

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## SECTION 7      Removing the PenFill 3 mL Cartridge

You will need to remove the PenFill cartridge for the following reasons:

- ~~When t~~he PenFill cartridge is empty.
- **If you use a suspension insulin such as Novolin N or Novolin 70/30:**

When you see the rear rubber stopper in the inspection window, then you do not have enough insulin left in the PenFill cartridge for proper mixing.

### Remove the barrel:

1. Remove the pen cap.
2. Hold the NovoPen 3 Demi with the dose indicator window at the top.
3. Unscrew the barrel from the cartridge holder.



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513 **SECTION 7 (cont.)**

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515 **Remove the PenFill 3 mL cartridge:**

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517 4. Tip the cartridge holder. The PenFill cartridge will drop out.

518

519 5. Press the push button all the way in until zero (0) appears in the window.

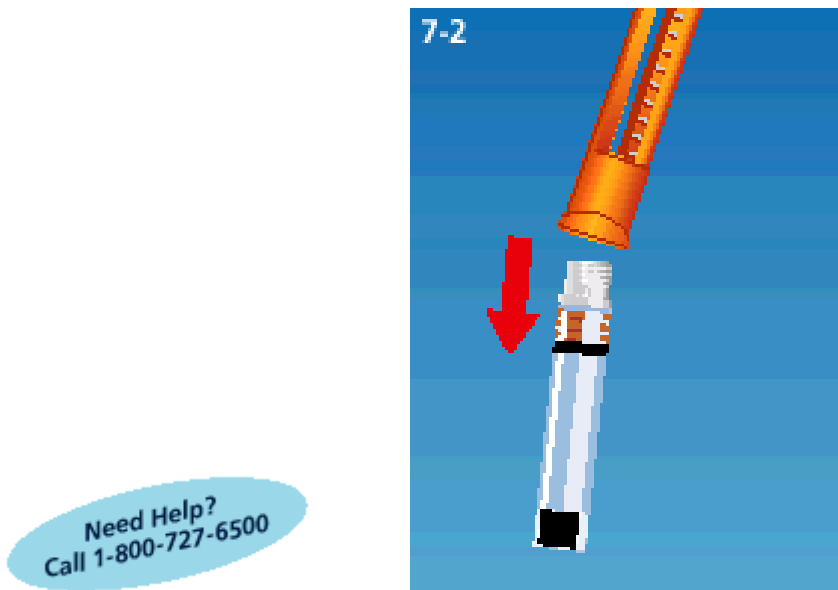
520

521 6. Turn the end of the reset mechanism in a clockwise direction until the  
522 piston rod is no longer sticking out (refer to figure 1-4 on page 7).

523

524 7. To insert a new PenFill cartridge, please refer to Section 2.

525



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527

528 **If the reset mechanism locks, it is usually due to improper technique. Gently turn**  
529 **the mechanism side to side until it unlocks and then call our toll free number (1-**  
530 **800-727-6500) so that we may go over your technique with you.**

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532



533

## **FUNCTION CHECK**

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535

You should regularly check the functioning of your NovoPen 3 Demi, (for example, once a month or before starting a new box of PenFill cartridges). The function check is done by delivering 20 units of insulin into the outer needle cap.

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538

You will not be injecting insulin into your body.

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540

Always check the functioning of the NovoPen 3 Demi if you suspect it has been damaged or if you are uncertain that it is delivering the correct dose.

541

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543

Do not use NovoPen 3 Demi unless you are sure that it is working properly.

544

545

### **To perform the function check:**

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1. Attach a NovoFine disposable needle(see pages 12-15).

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2. Do an air shot (see pages 16-19).

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**FUNCTION CHECK (cont.)**

3. **Do not replace the inner needle cap.** Place the outer needle cap securely over the exposed NovoFine needle.



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**Expel 20 units of insulin into the outer needle cap:**

4. Turn the dial-a-dose selector so the dose indicator window shows 20.



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Call 1-800-727-6500

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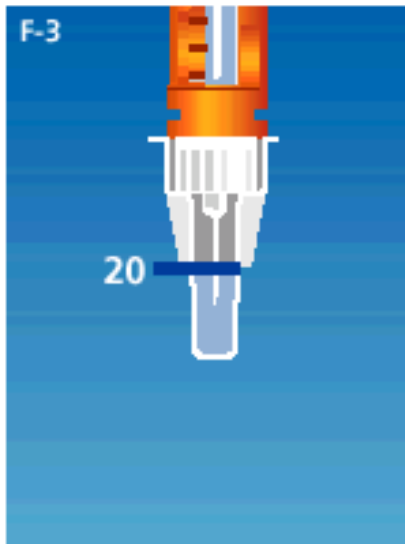
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570 **FUNCTION CHECK (cont.)**

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5. Hold the NovoPen 3 Demi so the NovoFine disposable needle is pointing down.
6. Slowly press the push button **as far as it will go**.
7. Check the dose indicator window to see if it shows zero (0). If it does not show zero (0), there is not enough insulin in the cartridge to do a function check. Insert a new PenFill cartridge (see pages 8-11) and repeat the function check. If there is enough insulin in the cartridge but the dose indicator window does not show zero, repeat the FUNCTION CHECK. If you do not see zero after repeating the above steps, do not use your NovoPen 3 Demi. Contact Novo Nordisk Pharmaceuticals, Inc. at our toll free number (1-800-727-6500).



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The insulin should fill the bottom part of the outer needle cap. This indicates the device is functioning properly.

If the insulin **does not fill or overfills** this part of the cap, review the function check procedure. Then repeat the function check with a new NovoFine disposable needle and outer needle cap.

If the second function check also shows under- or over-filling, do not use your NovoPen 3 Demi.

**DO NOT try to repair a NovoPen 3 Demi that you think is not working properly.**

See Warranty section for further information.



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## STORAGE

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### Guidelines for storing the NovoPen 3 Demi and PenFill 3 mL cartridges:

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- PenFill cartridges should be stored in a cool place, such as in a refrigerator, but not in ~~the~~a freezer.

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- After the first use of PenFill cartridge in the NovoPen 3 Demi, the NovoPen 3 Demi (with the PenFill cartridge inside) can be kept at room temperature below 86°F (30°C) for the amount of time-days specified listed in the PenFill Information for the Patient leaflet for the type of insulin you are using.

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- **Do not store** the NovoPen 3 Demi (with the PenFill cartridge inside) in a refrigerator or areas where there may be extreme temperatures or moisture, such as in your car.

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- **The expiration date printed on the cartridge is for unused cartridges under refrigeration. Never use the cartridge after the expiration date on the cartridge or its box.**

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- Store the NovoPen 3 Demi **without** the NovoFine needle attached and **with** the pen cap in position.

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- For information on storing PenFill cartridges, see the package leaflet that comes in the PenFill cartridge box.

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634 **MAINTENANCE**

635

636 **Guidelines for maintaining the NovoPen 3 Demi.**

637

638 **Be sure to:**

639

640 1. Clean it by wiping with a soft cloth moistened with alcohol.

641

642 2. Protect it from dust, dirt, and moisture when not in its case.

643

644

645 **Make certain you:**

646

647 1. **Do not** soak it in alcohol, do not wash it in soap and water, or do not  
648 lubricate it, since this may cause damage.

649

650 2. **Do not** expose it to excessive pressure or blows.

651

652 3. **Do not** drop it.

653

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655 **IMPORTANT THINGS TO KNOW**

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- The NovoPen 3 Demi is not recommended for the blind or visually impaired, without the assistance of a sighted individual trained to use it.

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- If you use more than one type of insulin (such as Novolin R, Novolin N, or Novolin 70/30, or NovoLog), use a separate insulin delivery device for each type of insulin.

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- Use only a new PenFill 3 mL cartridge when loading the NovoPen 3 Demi. Never load the NovoPen 3 Demi with a partially filled PenFill cartridge.

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- Always keep a spare insulin delivery system available, in case your NovoPen 3 Demi is lost or damaged.

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- Keep the NovoPen 3 Demi, PenFill cartridges, and NovoFine needles out of the reach of children. The American Diabetes Association recommends that insulin should be self-administered. The proper age for initiating this should be assessed by the adult caregiver.

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- Keep the NovoPen 3 Demi away from areas where temperatures may get too hot or too cold such as a car or refrigerator.

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- The NovoPen 3 Demi is designed for use with PenFill 3 mL insulin cartridges and NovoFine single-use disposable needles.

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Novo Nordisk is not responsible for any consequences arising from the use of the NovoPen 3 Demi with products other than PenFill 3 mL insulin cartridges and NovoFine single-use disposable needles.

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## **IMPORTANT NOTES**

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**The following is a review of some important information about the use and care of your NovoPen 3 Demi.**

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### **Before each injection, be certain:**

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1. The NovoPen 3 Demi contains the correct insulin cartridge (such as Novolin R, Novolin N, Novolin 70/30, or NovoLog), if you use more than one type of insulin.

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2. The PenFill cartridge contains enough insulin for mixing, if you use a suspension insulin (white and cloudy) such as Novolin N or Novolin 70/30.

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3. To do an air shot with the NovoFine needle pointing up before each injection.

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### **Be sure to:**

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1. Check the dose indicator window after each injection to make sure you have received your full dose (see page 23, Section 5).

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2. Remove the NovoFine needle immediately after each injection without replacing the cap.

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3. Select your dose only by using the number in the dose indicator window.

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4. Perform the function check regularly or if you think your NovoPen 3 Demi is not working properly.

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720 **IMPORTANT NOTES (cont.)**

721

722 **Make certain you:**

723

724 1. **DO NOT** place a NovoFine needle on the NovoPen 3 Demi until you are  
725 ready to do an air shot and give an injection or do a function check.

726 Remove the needle immediately after each injection without recapping the  
727 needle. If the NovoFine needle is not removed, some liquid may leak out  
728 of the PenFill cartridge. This may cause a change in the strength of  
729 suspension insulin (white and cloudy) such as Novolin N or Novolin  
730 70/30.

731

732 2. **DO NOT** use the clicking sound to set your insulin dose.

733

734 3. **DO NOT** try to refill a PenFill cartridge.

735

736 4. **DO NOT** share the same PenFill cartridge with anyone else even if you  
737 attach a new NovoFine needle for each injection. Sharing cartridge can  
738 spread disease. Each PenFill cartridge is for single-person use only.

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740 Blood glucose levels should be tested frequently to monitor your insulin regimen.

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742 **Any change in insulin should be made cautiously and only under medical**  
743 **supervision.**

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**WHAT TO DO IF...**

**The dose indicator window does not show zero after the injection:**

1. **You did not receive your full dose.**  
Follow the steps on page 23 to get the remaining part of your dose.
2. **Your NovoPen 3 Demi is malfunctioning.**  
Do not use your NovoPen 3 Demi. Contact Novo Nordisk Pharmaceuticals, Inc. at our toll free number (1-800-727-6500).

**No insulin appears when you do the air shot:**

1. **The piston rod is not far enough down the cartridge holder to reach the rear rubber stopper.**  
Repeat the air shot (see pages 16-19).
2. **The NovoFine needle may not be securely attached.**
  - a. Put the plastic outer cap back on the NovoFine needle.
  - b. Turn the plastic outer cap in a clockwise direction to tighten the NovoFine needle.
3. **The NovoFine needle may be blocked.**  
Change the NovoFine needle (see pages 14-15) and do an air shot (see pages 16-19).

**The piston rod is sticking out too far to attach the cartridge holder to the barrel:**

You must screw the piston rod back into the barrel (see page 7). Never try to push it in or you can damage the mechanism.

**The push button will not return to zero or the piston rod will not turn back into the reset mechanism:**

The return mechanism may be locked. This is usually due to improper technique. Gently turn the mechanism side to side until it unlocks and then call our toll free number (1-800-727-6500) so that we may review go over your technique with you.

788 **WARRANTY**

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Should your NovoPen® 3 Demi device be defective in materials or workmanship within two (2) years of purchase, Novo Nordisk Pharmaceuticals, Inc. will replace it at no charge if you mail the defective unit along with a description of the problem and the sales receipt or other proof of purchase to:

**Novo Nordisk Pharmaceuticals, Inc.**

**Product Safety**

**100 College Road West**

**Princeton, NJ 08540**

Protected by U.S. Patent Nos. 5,693,027; 5,626,566; 6,126,646 and Des. 347,894 (cartridge) restricted to use with Novo Nordisk insulin cartridges and Novo Nordisk pen needles.

No other warranty is made with respect to NovoPen® 3 Demi. This warranty will be invalid and Novo Nordisk A/S, Novo Nordisk Pharmaceuticals, Inc., Bristol-Myers Squibb Co., Nipro Medical Industries Ltd., and Bang & Olufsen A/S cannot be held responsible in the case of defects or damages arising from:

- The use of the NovoPen® 3 Demi with products other than PenFill 3 mL cartridges and NovoFine single-use disposable needles.
- The use of the NovoPen® 3 Demi not in accordance with the instructions in this booklet.
- Physical damage to the NovoPen® 3 Demi caused by neglect, misuse, unauthorized repair, accident, or other breakage.

819 For assistance or further information, write to:

820

821 **Novo Nordisk Pharmaceuticals, Inc.**

822 **Customer Relations**

823 **100 College Road West**

824 **Princeton, NJ 08540**

825

826 **Or call: 1-800-727-6500**

827

828

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834 ***Novo Nordisk Pharmaceuticals, Inc.***

835 Princeton, NJ 08540

836

837 <http://www.novonordisk-us.com>

838

839 8-4241-31-002-1

840

841

**R** HUMAN

Information for the patient who uses

**Novolin® R PenFill®**

Regular,  
Human Insulin Injection  
(recombinant DNA origin)  
3 mL Disposable Cartridge  
(300 units per cartridge)

**100** units/mL

Please read this leaflet carefully before using this product. Please note the special directions under "PREPARING THE INJECTION". Novolin® R PenFill® 3 mL is designed for use with NovoPen® 3 Insulin Delivery Device and NovoFine® disposable needles or other products specifically recommended by Novo Nordisk. PenFill® cartridge is for single person use only. See Important Notes section.

Devices

→ NovoPen® Junior, and NovoPen® 3 Demi

**WARNING**

ANY CHANGE OF INSULIN SHOULD BE MADE CAUTIOUSLY AND ONLY UNDER MEDICAL SUPERVISION. CHANGES IN PURITY, STRENGTH, BRAND (MANUFACTURER), TYPE (REGULAR, NPH, LENTE, ETC.), SPECIES (BEEF, PORK, BEEF-PORK, HUMAN), AND/OR METHOD OF MANUFACTURE (RECOMBINANT DNA VERSUS ANIMAL-SOURCE INSULIN) MAY RESULT IN THE NEED FOR A CHANGE IN DOSAGE.

SPECIAL CARE SHOULD BE TAKEN WHEN THE TRANSFER IS FROM A STANDARD BEEF OR MIXED SPECIES INSULIN TO A PURIFIED PORK OR HUMAN INSULIN. IF A DOSAGE ADJUSTMENT IS NEEDED, IT WILL USUALLY BECOME APPARENT EITHER IN THE FIRST FEW DAYS OR OVER A PERIOD OF SEVERAL WEEKS. ANY CHANGE IN TREATMENT SHOULD BE CAREFULLY MONITORED.

PLEASE READ THE SECTIONS "INSULIN REACTION AND SHOCK" AND "DIABETIC KETOACIDOSIS AND COMA" FOR SYMPTOMS OF HYPOGLYCEMIA (LOW BLOOD GLUCOSE) AND HYPERGLYCEMIA (HIGH BLOOD GLUCOSE).

**INSULIN USE IN DIABETES**

Your physician has explained that you have diabetes and that your treatment involves injections of insulin or insulin therapy combined with an oral antidiabetic medicine. Insulin is normally produced by the pancreas, a gland that lies behind the stomach. Without insulin, glucose (a simple sugar made from digested food) is trapped in the bloodstream and cannot enter the cells of the body. Some patients who don't make enough of their own insulin, or who cannot use the insulin they do make properly, must take insulin by injection in order to control their blood glucose levels.

Each case of diabetes is different and requires direct and continued medical supervision. Your physician has told you the type, strength and amount of insulin you should use and the time(s) at which you should inject it, and has also discussed with you a diet and exercise schedule. You should contact your physician if you experience any difficulties or if you have questions.

**TYPES OF INSULINS**

Standard and purified animal insulins as well as human insulins are available. Standard and purified insulins differ in their degree of purification and content of noninsulin material. Standard and purified insulins also vary in species source: they may be of beef, pork, or mixed beef and pork origin. Human insulin is identical in structure to the insulin produced by the human pancreas, and thus differs from animal insulins. Insulins vary in time of action; see PRODUCT DESCRIPTION for additional information.

Your physician has prescribed the insulin that is right for you; be sure you have purchased the correct insulin and check it carefully before you use it.

**PRODUCT DESCRIPTION**

This package contains five (5) Novolin® R PenFill® 3 mL cartridges. Novolin® R is commonly known as Regular, Human Insulin Injection (recombinant DNA origin). The concentration of this product is 100 units of insulin per milliliter. It is a clear, colorless solution which has a short duration of action. The effect of Novolin® R begins approximately ½ hour after injection. The effect is maximal between 2½ and 5 hours and ends approximately 8 hours after injection.

The time course of action of any insulin may vary considerably in different individuals, or at different times in the same individual. Because of this variation, the time periods listed here should be considered as general guidelines only.

This human insulin (recombinant DNA origin) is structurally identical to the insulin produced by the human pancreas. This human insulin is produced by recombinant DNA technology utilizing *Saccharomyces cerevisiae* (bakers' yeast) as the production organism.

**INSULIN DELIVERY SYSTEMS**

These Novolin® R PenFill® 3 mL cartridges are designed for use with NovoPen® 3 Insulin Delivery Device and NovoFine® disposable needles or other products specifically recommended by Novo Nordisk.

**STORAGE**

Insulin should be stored in a cold place, preferably in a refrigerator, but not in the freezing compartment. Do not let it freeze. Keep Novolin® R PenFill® cartridges in the carton so that they will stay clean and protected from light. Novolin® R PenFill® cartridges can be kept unrefrigerated for 28 days. Unrefrigerated cartridges must be used within this time period or discarded. Be sure to protect cartridges from sunlight and extreme heat or cold.

Never use any Novolin® R PenFill® cartridge if it becomes viscous (thickened) or cloudy; use it only if it is clear and colorless.

Never use insulin after the expiration date which is printed on the label and carton.

**IMPORTANT**

Failure to comply with the following antiseptic measures may lead to infections at the injection site.

- Disposable needles are for single use; they should be used only once and destroyed.
- Clean your hands and the injection site with soap and water or with alcohol.
- Wipe the rubber stopper on the insulin cartridge with an alcohol swab.

**PREPARING THE INJECTION**

Place a NovoFine® single-use needle on the device. Refer to the instruction manual for your insulin delivery device.

Insulin PenFill® cartridges may contain a small amount of air. To prevent an injection of air and make certain insulin is delivered, an air shot must be done before each injection.

Directions for performing an air shot are provided in your insulin delivery device instruction manual.

#### GIVING THE INJECTION

1. The following areas are suitable for subcutaneous insulin injection: thighs, upper arms, buttocks, abdomen. Do not change areas without consulting your physician. The actual point of injection should be changed each time; injection sites should be about an inch apart.
2. The injection site should be clean and dry. Pinch up skin area to be injected and hold it firmly.
3. Hold the device like a pencil and push the needle quickly and firmly into the pinched-up area.
4. Release the skin and push the push-button *all the way in* to inject insulin beneath the skin. To ensure that all the insulin is injected, *keep the needle in the skin* for several seconds after injection with your thumb on the push button. Do not inject into a muscle unless your physician has advised it. You should never inject insulin into a vein. Follow the directions for use of your Insulin Delivery Device.
5. Remove the needle. If slight bleeding occurs, press lightly with a dry cotton swab for a few seconds - **do not rub.**

Note: Use the injection technique recommended by your physician.

#### USAGE IN PREGNANCY

It is particularly important to maintain good control of your diabetes during pregnancy and special attention must be paid to your diet, exercise and insulin regimens. If you are pregnant or nursing a baby, consult your physician or nurse educator.

#### INSULIN REACTION AND SHOCK

Insulin reaction 'hypoglycemia' occurs when the blood glucose falls very low. This can happen if you take too much insulin, miss or delay a meal, exercise more than usual or work too hard without eating, or become ill (especially with vomiting or fever). Hypoglycemia can also happen if you combine insulin therapy and other medications that lower blood glucose, such as oral antidiabetic agents or other prescription and over-the-counter drugs. The first symptoms of an insulin reaction usually come on suddenly. They may include a cold sweat, fatigue, nervousness or shakiness, rapid heartbeat, or nausea. Personality change or confusion may also occur. If you drink or eat something right away (a glass of milk or orange juice, or several sugar candies), you can often stop the progression of symptoms. If symptoms persist, call your physician - an insulin reaction can lead to unconsciousness. If a reaction results in loss of consciousness, emergency medical care should be obtained immediately. If you have had repeated reactions or if an insulin reaction has led to a loss of consciousness, contact your physician. Severe hypoglycemia can result in temporary or permanent impairment of brain function and death.

In certain cases, the nature and intensity of the warning symptoms of hypoglycemia may change. A few patients have reported that after being transferred to human insulin, the early warning symptoms of hypoglycemia were less pronounced than they had been with animal-source insulin.

#### DIABETIC KETOACIDOSIS AND COMA

Diabetic ketoacidosis may develop if your body has too little insulin. The most common causes are acute illness or infection or failure to take enough insulin by injection. If you are ill you should check your urine for ketones. The symptoms of diabetic ketoacidosis usually come on gradually, over a period of hours or days, and include a drowsy feeling, flushed face, thirst and loss of appetite. Notify your physician right away if the urine test is positive for ketones (acetone) or if you have any of these symptoms. Fast, heavy breathing and rapid pulse are more severe symptoms and you should have medical attention right away. Severe, sustained hyperglycemia may result in diabetic coma and death.

#### ADVERSE REACTIONS

A few people with diabetes develop red, swollen and itchy skin where the insulin has been injected. This is called a 'local reaction' and it may occur if the injection is not properly made, if the skin is sensitive to the cleansing solution, or if you are allergic to the insulin being used. If you have a local reaction, tell your physician.

Generalized insulin allergy occurs rarely, but when it does it may cause a serious reaction, including skin rash over the body, shortness of breath, fast pulse, sweating, and a drop in blood pressure. If any of these symptoms develop, you should seek emergency medical care. If severe allergic reactions to insulin have occurred (i.e., generalized rash, swelling or breathing difficulties) you should be skin-tested with each new insulin preparation before it is used.

#### IMPORTANT NOTES

1. A change in the type, strength, species or purity of insulin could require a dosage adjustment. Any change in insulin should be made under medical supervision.
2. To avoid possible transmission of disease, PenFill cartridge is for single person use only.
3. Before use, check that the PenFill cartridge is intact (e.g. no cracks). Do not use if any damage is seen, or if the part of the rubber piston that you see is wider than the white bar code band.
4. You may have learned how to test your urine or your blood for glucose. It is important to do these tests regularly and to record the results for review with your physician or nurse educator.
5. If you have an acute illness, especially with vomiting or fever, continue taking your insulin. If possible, stay on your regular diet. If you have trouble eating, drink fruit juices, regular soft drinks, or clear soups; if you can, eat small amounts of bland foods. Test your urine for glucose and ketones and, if possible, test your blood glucose. Note the results and contact your physician for possible insulin dose adjustment. If you have severe and prolonged vomiting, seek emergency medical care.
6. You should always carry identification which states that you have diabetes.
7. Always ask your physician or pharmacist before taking any drug.
8. Do not try to refill a PenFill cartridge.

Always consult your physician if you have any questions about your condition or the use of insulin.

Helpful information for people with diabetes is published by American Diabetes Association, 1680 Duke Street, Alexandria, VA 22314

For information contact:  
Novo Nordisk Pharmaceuticals, Inc.  
100 Overlook Center  
Suite 200  
Princeton, NJ 08540  
1-800-727-6500

Manufactured by  
Novo Nordisk Pharmaceutical Industries, Inc.  
Clayton, NC 27520

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insulin delivery devices and Novo Nordisk pen needles.

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Printed in USA

NovoPen® Junior, and NovoPen® 3 Demi

Date of issue: February 2000

**N** HUMAN

Information for the patient who uses:

**Novolin® N PenFill®**

NPH, Human Insulin Isophane Suspension  
(recombinant DNA origin)  
3 mL Disposable Cartridge  
(300 units per cartridge)

**100** units/mL

Please read this leaflet carefully before using this product.  
Please note the special directions under "PREPARING THE INJECTION".  
Novolin® N PenFill® 3 mL is designed for use with NovoPen® 3 Insulin Delivery Device and NovoFine® disposable needles or other products specifically recommended by Novo Nordisk.  
PenFill® cartridge is for single person use only. See Important Notes section.

NovoPen® Junior, and NovoPen® 3 Demi

Devices

**WARNING**

ANY CHANGE OF INSULIN SHOULD BE MADE CAUTIOUSLY AND ONLY UNDER MEDICAL SUPERVISION. CHANGES IN PURITY, STRENGTH, BRAND (MANUFACTURER), TYPE (REGULAR, NPH, LEUTE, ETC.), SPECIES (BEEF, PORK, BEEF-PORK, HUMAN), AND/OR METHOD OF MANUFACTURE (RECOMBINANT DNA VERSUS ANIMAL-SOURCE INSULIN) MAY RESULT IN THE NEED FOR A CHANGE IN DOSAGE.  
SPECIAL CARE SHOULD BE TAKEN WHEN THE TRANSFER IS FROM A STANDARD BEEF OR MIXED SPECIES INSULIN TO A PURIFIED PORK OR HUMAN INSULIN. IF A DOSAGE ADJUSTMENT IS NEEDED, IT WILL USUALLY BECOME APPARENT EITHER IN THE FIRST FEW DAYS OR OVER A PERIOD OF SEVERAL WEEKS. ANY CHANGE IN TREATMENT SHOULD BE CAREFULLY MONITORED.  
PLEASE READ THE SECTIONS "INSULIN REACTION AND SHOCK" AND "DIABETIC KETOACIDOSIS AND COMA" FOR SYMPTOMS OF HYPOGLYCEMIA (LOW BLOOD GLUCOSE) AND HYPERGLYCEMIA (HIGH BLOOD GLUCOSE).

**INSULIN USE IN DIABETES**

Your physician has explained that you have diabetes and that your treatment involves injections of insulin or insulin therapy combined with an oral antidiabetic medicine. Insulin is normally produced by the pancreas, a gland that lies behind the stomach. Without insulin, glucose (a simple sugar made from digested food) is trapped in the bloodstream and cannot enter the cells of the body. Some patients who don't make enough of their own insulin, or who cannot use the insulin they do make properly, must take insulin by injection in order to control their blood glucose levels.  
Each case of diabetes is different and requires direct and continued medical supervision. Your physician has told you the type, strength and amount of insulin you should use and the time(s) at which you should inject it, and has also discussed with you a diet and exercise schedule. You should contact your physician if you experience any difficulties or if you have questions.

**TYPES OF INSULINS**

Standard and purified animal insulins as well as human insulins are available. Standard and purified insulins differ in their degree of purification and content of noninsulin material. Standard and purified insulins also vary in species source; they may be of beef, pork, or mixed beef and pork origin. Human insulin is identical in structure to the insulin produced by the human pancreas, and thus differs from animal insulins. Insulins vary in time of action; see PRODUCT DESCRIPTION for additional information.

Your physician has prescribed the insulin that is right for you; be sure you have purchased the correct insulin and check it carefully before you use it.

**PRODUCT DESCRIPTION**

This package contains five (5) Novolin® N PenFill® 3 mL cartridges. Novolin® N is commonly known as NPH, Human Insulin Isophane Suspension (recombinant DNA origin). The concentration of this product is 100 units of insulin per milliliter. It is a cloudy or milky suspension of human insulin with protamine and zinc. The insulin substance (the cloudy material) settles at the bottom of the cartridge, therefore, the cartridge must be rotated up and down as described under "PREPARING THE INJECTION" so that the contents are uniformly mixed before a dose is given. Novolin® N has an intermediate duration of action. The effect of Novolin® N begins approximately 1½ hours after injection. The effect is maximal between 4 and approximately 12 hours. The full duration of action may last up to 24 hours after injection.

The time course of action of any insulin may vary considerably in different individuals, or at different times in the same individual. Because of this variation, the time periods listed here should be considered as general guidelines only.  
This human insulin (recombinant DNA origin) is structurally identical to the insulin produced by the human pancreas. This human insulin is produced by recombinant DNA technology utilizing *Saccharomyces cerevisiae* (bakers' yeast) as the production organism.

**INSULIN DELIVERY SYSTEMS**

These Novolin® N PenFill® 3 mL cartridges are designed for use with NovoPen® 3 Insulin Delivery Device and NovoFine® disposable needles or other products specifically recommended by Novo Nordisk.

**STORAGE**

Insulin should be stored in a cold place, preferably in a refrigerator, but not in the freezing compartment. Do not let it freeze. Keep Novolin® N PenFill® cartridges in the carton so that they will stay clean and protected from light. Novolin® N PenFill® cartridges can be kept unrefrigerated for 14 days. Unrefrigerated cartridges must be used within this time period or discarded. Be sure to protect cartridges from sunlight and extreme heat or cold.  
Never use any Novolin® N PenFill® cartridge if the precipitate (the white deposit) has become lumpy or granular in appearance or has formed a deposit of solid particles on the wall of the cartridge. This insulin should not be used if the liquid in the cartridge remains clear after it has been mixed.

Never use insulin after the expiration date which is printed on the label and carton.

**IMPORTANT**

Failure to comply with the following aseptic measures may lead to infections at the injection site.

- Disposable needles are for single use; they should be used only once and destroyed.
- Clean your hands and the injection site with soap and water or with alcohol.
- Wipe the rubber stopper on the insulin cartridge with an alcohol swab.

**PREPARING THE INJECTION**

Never place a single-use needle on your insulin delivery device until you are ready to give an injection, and remove it immediately after each injection. If the needle is not removed, some liquid may be expelled from the cartridge causing a change in the insulin concentration (strength).

The cloudy material in an insulin suspension will settle to the bottom of the cartridge, so the contents must be mixed before injection. These Novolin® PenFill® cartridges contain a glass ball to aid mixing.

When using a new cartridge, turn the cartridge up and down between positions A and B - See Figure 1. Do this at least 10 times until the liquid appears uniformly white and cloudy. Assemble your insulin delivery device following the directions in your instruction manual. For subsequent injections when a cartridge is already in the device, turn the device up and down between positions A and B - See Figure 2. Do this at least 10 times until the liquid appears uniformly white and cloudy. Follow the directions in your insulin delivery device instruction manual.

0274-31-087-1



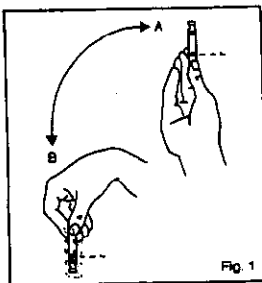


Fig. 1

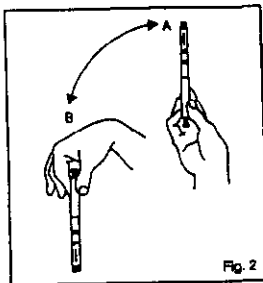


Fig. 2

Note: Never initiate a new injection unless there is sufficient insulin in the cartridge to ensure proper mixing (the glass ball needs adequate room for movement to mix the suspension). Insulin PenFill® cartridges may contain a small amount of air. To prevent an injection of air and make certain insulin is delivered, an air shot must be done before each injection. Directions for performing an air shot are provided in your delivery device instruction manual.

#### GIVING THE INJECTION

1. The following areas are suitable for subcutaneous insulin injection: thighs, upper arms, buttocks, abdomen. Do not change areas without consulting your physician. The actual point of injection should be changed each time; injection sites should be about an inch apart.
2. The injection site should be clean and dry. Pinch up skin area to be injected and hold it firmly.
3. Hold the device like a pencil and push the needle quickly and firmly into the pinched-up area.
4. Release the skin and push the push-button all the way in to inject insulin beneath the skin. To ensure that all the insulin is injected, keep the needle in the skin for several seconds after injection with your thumb on the push button. Do not inject into a muscle unless your physician has advised it. You should never inject insulin into a vein. Follow the directions for use of your Insulin Delivery Device.
5. Remove the needle. If slight bleeding occurs, press lightly with a dry cotton swab for a few seconds - do not rub.

Note: Use the injection technique recommended by your physician.

#### USAGE IN PREGNANCY

It is particularly important to maintain good control of your diabetes during pregnancy and special attention must be paid to your diet, exercise and insulin regimens. If you are pregnant or nursing a baby, consult your physician or nurse educator.

#### INSULIN REACTION AND SHOCK

Insulin reaction "hypoglycemia" occurs when the blood glucose falls very low. This can happen if you take too much insulin, miss or delay a meal, exercise more than usual or work too hard without eating, or become ill (especially with vomiting or fever). Hypoglycemia can also happen if you combine insulin therapy and other medications that lower blood glucose, such as oral antidiabetic agents or other prescription and over-the-counter drugs. The first symptoms of an insulin reaction usually come on suddenly. They may include a cold sweat, fatigue, nervousness or shakiness, rapid heartbeat, or nausea. Personality change or confusion may also occur. If you drink or eat something right away (a glass of milk or orange juice, or several sugar candies), you can often stop the progression of symptoms. If symptoms persist, call your physician - an insulin reaction can lead to unconsciousness. If a reaction results in loss of consciousness, emergency medical care should be obtained immediately. If you have had repeated reactions or if an insulin reaction has led to a loss of consciousness, contact your physician. Severe hypoglycemia can result in temporary or permanent impairment of brain function and death.

In certain cases, the nature and intensity of the warning symptoms of hypoglycemia may change. A few patients have reported that after being transferred to human insulin, the early warning symptoms of hypoglycemia were less pronounced than they had been with animal-source insulin.

#### DIABETIC KETOACIDOSIS AND COMA

Diabetic ketoacidosis may develop if your body has too little insulin. The most common causes are acute illness or infection or failure to take enough insulin by injection. If you are ill you should check your urine for ketones. The symptoms of diabetic ketoacidosis usually come on gradually, over a period of hours or days, and include a drowsy feeling, flushed face, thirst and loss of appetite. Notify your physician right away if the urine test is positive for ketones (acetone) or if you have any of these symptoms. Fast, heavy breathing and rapid pulse are more severe symptoms and you should have medical attention right away. Severe, sustained hyperglycemia may result in diabetic coma and death.

#### ADVERSE REACTIONS

A few people with diabetes develop red, swollen and itchy skin where the insulin has been injected. This is called a "local reaction" and it may occur if the injection is not properly made, if the skin is sensitive to the cleansing solution, or if you are allergic to the insulin being used. If you have a local reaction, tell your physician.

Generalized insulin allergy occurs rarely, but when it does it may cause a serious reaction, including skin rash over the body, shortness of breath, fast pulse, sweating, and a drop in blood pressure. If any of these symptoms develop, you should seek emergency medical care. If severe allergic reactions to insulin have occurred (i.e., generalized rash, swelling or breathing difficulties) you should be skin-tested with each new insulin preparation before it is used.

#### IMPORTANT NOTES

1. A change in the type, strength, species or purity of insulin could require a dosage adjustment. Any change in insulin should be made under medical supervision.
2. To avoid possible transmission of disease, PenFill® cartridge is for single person use only.
3. Before use, check that the PenFill® cartridge is intact (e.g., no cracks). Do not use if any damage is seen, or if the part of the rubber piston that you see is wider than the white bar code band.
4. You may have learned how to test your urine or your blood for glucose. It is important to do these tests regularly and to record the results for review with your physician or nurse educator.
5. If you have an acute illness, especially with vomiting or fever, continue taking your insulin. If possible, stay on your regular diet. If you have trouble eating, drink fruit juices, regular soft drinks, or clear soups; if you can, eat small amounts of bland foods. Test your urine for glucose and ketones and, if possible, test your blood glucose. Note the results and contact your physician for possible insulin dose adjustment. If you have severe and prolonged vomiting, seek emergency medical care.
6. You should always carry identification which states that you have diabetes.
7. Always ask your physician or pharmacist before taking any drug.
8. Do not try to refill a PenFill® cartridge.

Always consult your physician if you have any questions about your condition or the use of insulin.

Helpful information for people with diabetes is published by American Diabetes Association, 1660 Duke Street, Alexandria, VA 22314

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Clayton, NC 27520

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insulin delivery devices and Novo Nordisk pen needles.

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Printed in USA

NovoPen® Junior, and NovoPen® 3 Demi

Date of issue: February 2000

**70/30 HUMAN**

Information for the patient who uses

**Novolin® 70/30 PenFill®**

70% NPH, Human Insulin Isophane Suspension and  
30% Regular, Human Insulin Injection  
(recombinant DNA origin)  
3 mL Disposable Cartridge  
(300 units per cartridge)

**100** units/mL

Please read this leaflet carefully before using this product.

Please note the special directions under "PREPARING THE INJECTION".

Novolin® 70/30 PenFill® 3 mL is designed for use with NovoPen® 3 Insulin

Delivery Device and NovoFine® disposable needles or other products

specifically recommended by Novo Nordisk.

PenFill® cartridge is for single person use only. See Important Notes section.

**WARNING**

ANY CHANGE OF INSULIN SHOULD BE MADE CAUTIOUSLY AND ONLY UNDER MEDICAL SUPERVISION. CHANGES IN PURITY, STRENGTH, BRAND (MANUFACTURER), TYPE (REGULAR, NPH, LENTE, ETC.), SPECIES (BEEF, PORK, BEEF-PORK, HUMAN), AND/OR METHOD OF MANUFACTURE (RECOMBINANT DNA VERSUS ANIMAL-SOURCE INSULIN) MAY RESULT IN THE NEED FOR A CHANGE IN DOSAGE.

SPECIAL CARE SHOULD BE TAKEN WHEN THE TRANSFER IS FROM A STANDARD BEEF OR MIXED SPECIES INSULIN TO A PURIFIED PORK OR HUMAN INSULIN. IF A DOSAGE ADJUSTMENT IS NEEDED, IT WILL USUALLY BECOME APPARENT EITHER IN THE FIRST FEW DAYS OR OVER A PERIOD OF SEVERAL WEEKS. ANY CHANGE IN TREATMENT SHOULD BE CAREFULLY MONITORED.

PLEASE READ THE SECTIONS "INSULIN REACTION AND SHOCK" AND "DIABETIC KETOACIDOSIS AND COMA" FOR SYMPTOMS OF HYPOGLYCEMIA (LOW BLOOD GLUCOSE) AND HYPERGLYCEMIA (HIGH BLOOD GLUCOSE).

**INSULIN USE IN DIABETES**

Your physician has explained that you have diabetes and that your treatment involves injections of insulin or insulin therapy combined with an oral antidiabetic medicine. Insulin is normally produced by the pancreas, a gland that lies behind the stomach. Without insulin, glucose (a simple sugar made from digested food) is trapped in the bloodstream and cannot enter the cells of the body. Some patients who don't make enough of their own insulin, or who cannot use the insulin they do make properly, must take insulin by injection in order to control their blood glucose levels.

Each case of diabetes is different and requires direct and continued medical supervision. Your physician has told you the type, strength and amount of insulin you should use and the time(s) at which you should inject it, and has also discussed with you a diet and exercise schedule. You should contact your physician if you experience any difficulties or if you have questions.

**TYPES OF INSULINS**

Standard and purified animal insulins as well as human insulins are available. Standard and purified insulins differ in their degree of purification and content of noninsulin material. Standard and purified insulins also vary in species source: they may be of beef, pork, or mixed beef and pork origin. Human insulin is identical in structure to the insulin produced by the human pancreas, and thus differs from animal insulins. Insulins vary in time of action; see PRODUCT DESCRIPTION for additional information. Your physician has prescribed the insulin that is right for you; be sure you have purchased the correct insulin and check it carefully before you use it.

**PRODUCT DESCRIPTION**

This package contains five (5) Novolin® 70/30 PenFill® 3 mL cartridges. Novolin® 70/30 is a mixture of 70% NPH, Human Insulin Isophane Suspension (recombinant DNA origin) and 30% Regular, Human Insulin Injection (recombinant DNA origin). The concentration of this product is 100 units of insulin per milliliter. It is a cloudy or milky suspension of human insulin with protamine and zinc. The insulin substance (the cloudy material) settles at the bottom of the cartridge, therefore, the cartridge must be rotated up and down as described under "PREPARING THE INJECTION" so that the contents are uniformly mixed before a dose is given. Novolin® 70/30 has an intermediate duration of action. The effect of Novolin® 70/30 begins approximately ½ hour after injection. The effect is maximal between 2 and approximately 12 hours. The full duration of action may last up to 24 hours after injection.

The time course of action of any insulin may vary considerably in different individuals, or at different times in the same individual. Because of this variation, the time periods listed here should be considered as general guidelines only.

This human insulin (recombinant DNA origin) is structurally identical to the insulin produced by the human pancreas. This human insulin is produced by recombinant DNA technology utilizing *Saccharomyces cerevisiae* (bakers' yeast) as the production organism.

**INSULIN DELIVERY SYSTEMS**

These Novolin® 70/30 PenFill® 3 mL cartridges are designed for use with NovoPen® 3 Insulin Delivery Device and NovoFine® disposable needles or other products specifically recommended by Novo Nordisk.

**STORAGE**

Insulin should be stored in a cold place, preferably in a refrigerator, but not in the freezing compartment. Do not let it freeze. Keep Novolin® 70/30 PenFill® cartridges in the carton so that they will stay clean and protected from light. Novolin® 70/30 PenFill® cartridges can be kept unrefrigerated for 10 days. Unrefrigerated cartridges must be used within this time period or discarded. Be sure to protect cartridges from sunlight and extreme heat or cold.

Never use any Novolin® 70/30 PenFill® cartridge if the precipitate (the white deposit) has become lumpy or granular in appearance or has formed a deposit of solid particles on the wall of the cartridge. This insulin should not be used if the liquid in the cartridge remains clear after it has been mixed.

Never use insulin after the expiration date which is printed on the label and carton.

**IMPORTANT**

Failure to comply with the following antiseptic measures may lead to infections at the injection site.

- Disposable needles are for single use; they should be used only once and destroyed.
- Clean your hands and the injection site with soap and water or with alcohol.
- Wipe the rubber stopper on the insulin cartridge with an alcohol swab.

**PREPARING THE INJECTION**

Never place a single-use needle on your insulin delivery device until you are ready to give an injection, and remove it immediately after each injection. If the needle is not removed, some liquid may be expelled from the cartridge causing a change in the insulin concentration (strength).

The cloudy material in an insulin suspension will settle to the bottom of the cartridge, so the contents must be mixed before injection. These Novolin® PenFill® cartridges contain a glass ball to aid mixing. When using a new cartridge, turn the cartridge up and down between positions A and B - See Figure 1. Do this at least 10 times until the liquid appears uniformly white and cloudy. Assemble your insulin delivery device following the directions in your instruction manual. For subsequent injections when a cartridge is already in the device, turn the device up and down between positions A and B - See Figure 2. Do this at least 10 times until the liquid appears uniformly white and cloudy. Follow the directions in your insulin delivery device instruction manual.

Devices

NovoPen® Junior, and NovoPen® 3 Demi

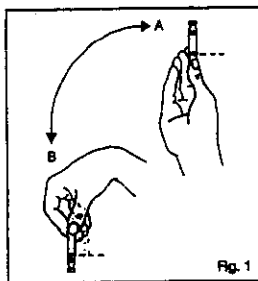


Fig. 1

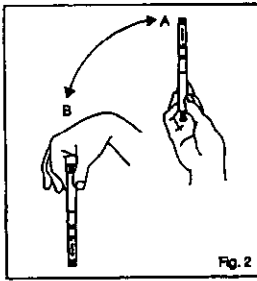


Fig. 2

Note: Never initiate a new injection unless there is sufficient insulin in the cartridge to ensure proper mixing (the glass ball needs adequate room for movement to mix the suspension). Insulin PenFill cartridges may contain a small amount of air. To prevent an injection of air and make certain insulin is delivered, an air shot must be done before each injection. Directions for performing an air shot are provided in your insulin delivery device instruction manual.

**GIVING THE INJECTION**

1. The following areas are suitable for subcutaneous insulin injection: thighs, upper arms, buttocks, abdomen. Do not change areas without consulting your physician. The actual point of injection should be changed each time; injection sites should be about an inch apart.
2. The injection site should be clean and dry. Pinch up skin area to be injected and hold it firmly.
3. Hold the device like a pencil and push the needle quickly and firmly into the pinched-up area.
4. Release the skin and push the push-button all the way in to inject insulin beneath the skin. To ensure that all the insulin is injected, keep the needle in the skin for several seconds after injection with your thumb on the push button. Do not inject into a muscle unless your physician has advised it. You should never inject insulin into a vein. Follow the directions for use of your Insulin Delivery Device.
5. Remove the needle. If slight bleeding occurs, press lightly with a dry cotton swab for a few seconds - do not rub.

Note: Use the injection technique recommended by your physician.

**USAGE IN PREGNANCY**

It is particularly important to maintain good control of your diabetes during pregnancy and special attention must be paid to your diet, exercise and insulin regimens. If you are pregnant or nursing a baby, consult your physician or nurse educator.

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NovoPen® Junior, and NovoPen® 3 Demi

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/s/

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David Orloff

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