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Current Insert 411042 February, 2002	Proposed Insert XXXXXX Month, 2002	Comments
Endo [®]	the state of the s	
ENDO LABORATORIES	The second section of the second section is the second section of the sect	
PERCOCET®	[TRADENAME]	
(Oxycodone and	(Oxycodone and	
Acetaminophen Tablets, USP)	Acetaminophen Tablets, USP) 15 mg/325 mg	
The state of the s	[TRADENAME]	
	(Oxycodone and Acetaminophen Tablets, USP) 20 mg/325 mg	
CII	CII	
only	R _x only	
SCRIPTION	DESCRIPTION	
ich tablet, for oral ministration, contains cycodone hydrochloride and	Each tablet, for oral administration, contains oxycodone hydrochloride and	
etaminophen in the	acetaminophen in the following strengths:	
llowing strengths: xycodone Hydrochloride	Oxycodone Hydrochloride	Change Oxycodone
7.5 mg*	15 mg*	Hydrochloride strength
cetaminophen, USP 325 mg	Acetaminophen, USP 325 mg	Service Control of the Control of th
5 mg oxycodone HCl is	*15 mg oxycodone HCl is	mange equivalent to 13.4456
juivalent to 6.7228 mg of cycodone.	equivalent to 13.4456 mg of oxycodone.	g of oxycodon
xycodone Hydrochloride 10 mg*	Oxycodone Hydrochloride 20 mg*	Change Oxycodone Hydrochloridestrength
cetaminophen, USP 325 mg	Acetaminophen, USP 325 mg	The state of the s
0 mg oxycodone HCI is juivalent to 8.9637 mg of ycodone.	*20 mg oxycodone HCI is equivalent to 17.9274 mg of oxycodone.	Change equivalent to 17.9274 mg of oxycodone
oth strengths of PERCOCET so contain the following active ingredients: Colloidal icon dioxide, croscarmellose dium, crospovidone, icrocrystaline cellulose, ovidone, pregelatinized arch, and stearic acid. In didition, the 7.5 mg/325 mg rength contains FD&C Yellow	Both strengths of [TRADENAME] also contain the following inactive ingredients:	Add inactive ingredients
o. 6 Aluminum Lake and the mg/325 mg strength ntains D&C Yellow No. 10 uminum Lake. etaminophen, 4'-droxyacetanilide, is a noniate, non-salicylate analgesic d antipyretic which occurs as white, odorless, crystalline wder, possessing a slightly	Acetaminophen, 4'- hydroxyacetanilide, is a non- opiate, non-salicylate analgesic and antipyretic which occurs as a white, odorless, crystalline powder, possessing a slightly	

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formula for acetaminophen is	formula for acetaminophen is	
C ₈ H ₉ NO ₂ and the molecular	C ₈ H ₉ NO ₂ and the molecular	
weight is 151.17. It may be	weight is 151.17. It may be	
represented by the following	represented by the following	
structural formula:	structural formula:	
онати	анафин ————————————————————————————————————	
Oxycodone, 14-	Oxycodone, 14-	
hydroxydihydrocodeinone, is a	hydroxydihydrocodeinone, is a	
semisynthetic opioid analgesic	semisynthetic opioid analgesic	
which occurs as a white,	which occurs as a white,	
odorless, crystalline powder	odorless, crystalline powder	
having a saline, bitter taste.	having a saline, bitter taste.	
The molecular formula for	The molecular formula for	
oxycodone hydrochloride is	oxycodone hydrochloride is	
C ₁₈ H ₂ 1NO ₄ •HCl and the	C ₁₈ H ₂ 1NO ₄ •HCl and the	
molecular weight 351.83. It is	molecular weight 351.83. It is	
derived from the opium	derived from the opium	
alkaloid thebaine, and may be	alkaloid thebaine, and may be	·
represented by the following	represented by the following	·
structural formula:	structural formula:	
Approximate the control of the contr	u openion de la company de la	
N-CH ₃	N-CH ₃	
HO	HO-	
• HCI	HCI	
H ₃ CO O O	H ₃ CO O 0	·
	1 3 5 5 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
CLINICAL PHARMACOLOGY	CLINICAL PHARMACOLOGY	
The principal ingredient,	The principal ingredient,	
oxycodone, is a semisynthetic	oxycodone, is a semisynthetic	
opioid analgesic with multiple	opioid analgesic with multiple	
actions qualitatively similar to	actions qualitatively similar to	
those of morphine; the most	those of morphine; the most	
prominent involves the central	prominent involves the central	
nervous system and organs	nervous system and organs	
composed of smooth muscle.	composed of smooth muscle.	
The principal actions of	The principal actions of	
therapeutic value of the	therapeutic value of the	
oxycodone in PERCOCET are	oxycodone in [TRADENAME]	
analgesia and sedation.	are analgesia and sedation.	
Oxycodone is similar to	Oxycodone is similar to	
codeine and methadone in that	codeine and methadone in that	
it retains at least one-half of its	it retains at least one-half of its	
analgesic activity when	analgesic activity when	
administered orally.	administered orally.	20 - 10 - 10 - 10 - 10 - 10 - 10 - 10 -
Acetaminophen is a non-	Acetaminophen is a non-	
opiate, non-salicylate analgesic		
and antipyretic.	and antipyretic.	
INDICATIONS AND USAGE	INDICATIONS AND USAGE	
PERCOCET is indicated for the	[TRADENAME] is indicated for	

and the contribution of the contribution of the property of the property of the contribution of the contri

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ief of moderate to	the relief of moderate to	The second secon
derately severe pain.	moderately severe pain.	The second secon
NTRAINDICATIONS	CONTRAINDICATIONS	
RCOCET should not be	[TRADENAME] should not be	
ministered to patients who	administered to patients who	
e hypersensitive to	are hypersensitive to	
kycodone, acetaminophen, or	oxycodone, acetaminophen, or	
ny other components of this	any other components of this	
oduct.	product.	
ARNINGS	WARNINGS	
rug Dependence	Drug Dependence	
xycodone can produce drug	Oxycodone can produce drug	
ependence of the morphine	dependence of the morphine	
pe and, therefore, has the	type and, therefore, has the	
otential for being abused.	potential for being abused.	
sychic dependence, physical	Psychic dependence, physical	
lependence and tolerance may	dependence and tolerance may	
evelop upon repeated	develop upon repeated	
dministration of PERCOCET	administration of	
Oxycodone and	[TRADENAME] (Oxycodone	
cetaminophen Tablets, USP),	and Acetaminophen Tablets,	
nd it should be prescribed and	USP), and it should be	
	prescribed and administered	
dministered with the same	with the same degree of	
egree of caution appropriate	caution appropriate to the use	
the use of other oral opioid-		
containing medications. Like	of other oral opioid-containing	
ther opioid-containing	medications. Like other opioid-	
nedications, PERCOCET is	containing medications,	
subject to the Federal	[TRADENAME] is subject to	
ontrolled Substances Act	the Federal Controlled	
Schedule II).	Substances Act (Schedule II).	
RECAUTIONS	PRECAUTIONS	
eneral	General	
lead Injury and Increased	Head Injury and Increased	
ntracranial Pressure: The	Intracranial Pressure: The	
espiratory depressant effects	respiratory depressant effects	
f opioids and their capacity to	of opioids and their capacity to	
evate cerebrospinal fluid	elevate cerebrospinal fluid	
ressure may be markedly	pressure may be markedly	
xaggerated in the presence	exaggerated in the presence	
f head injury, other	of head injury, other	
ntracranial lesions or a pre-	intracranial lesions or a pre-	
xisting increase in intracranial	existing increase in intracranial	
ressure. Furthermore, opioids	pressure. Furthermore, opioids	
roduce adverse reactions	produce adverse reactions	
hich may obscure the clinical	which may obscure the clinical	
course of patients with head	course of patients with head	
	injuries.	
njuries. Acute Abdominal	Acute Abdominal	
	Conditions: The	
	the state of the s	
Conditions: The		
administration of PERCOCET	administration of	
	[TRADENAME] or other opioids may obscure the diagnosis or	

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in patients with acute	clinical course in patients with	A Company of the Comp	
abdominal conditions.	acute abdominal conditions.		
Special Risk Patients:	Special Risk Patients:	The state of the s	
PERCOCET should be given	[TRADENAME] should be		
with caution to certain patients	given with caution to certain		
such as the elderly or	patients such as the elderly or		
debilitated, and those with	debilitated, and those with		
severe impairment of hepatic or	severe impairment of hepatic or		
renal function, hypothyroidism,	renal function, hypothyroidism,		
Addison's disease, and	Addison's disease, and		
prostatic hypertrophy or	prostatic hypertrophy or		
urethral stricture.	urethral stricture.		
Information for Patients	Information for Patients	The second secon	
Oxycodone may impair the	Oxycodone may impair the		
mental and/or physical abilities	mental and/or physical abilities		
required for the performance	required for the performance		
of potentially hazardous tasks	of potentially hazardous tasks		
such as driving a car or	such as driving a car or		
operating machinery. The	operating machinery. The		
patient using PERCOCET	patient using [TRADENAME]		
should be cautioned	should be cautioned		
accordingly.	accordingly.		
Drug Interactions	Drug Interactions	The second secon	
Patients receiving other opioid	Patients receiving other opioid		
analgesics, general	analgesics, general		
anesthetics, phenothiazines,	anesthetics, phenothiazines,		
other tranquilizers, sedative-	other tranquilizers, sedative-		
hypnotics or other CNS	hypnotics or other CNS		
depressants (including	depressants (including		
alcohol) concomitantly with	alcohol) concomitantly with		
PERCOCET may exhibit an	[TRADENAME] may exhibit an		
additive CNS depression.	additive CNS depression.		
When such combined therapy	When such combined therapy		
is contemplated, the dose of	is contemplated, the dose of		
one or both agents should be	one or both agents should be		
reduced.	reduced.	i	
The concurrent use of	The concurrent use of		1
anticholinergics with opioids	anticholinergics with opioids		
may produce paralytic ileus.	may produce paralytic ileus.		
Usage in Pregnancy	Usage in Pregnancy		†
Teratogenic Effects;	Teratogenic Effects;		
Pregnancy Category C:	Pregnancy Category C:		
Animal reproductive studies	Animal reproductive studies		
have not been conducted with	have not been conducted with		
PERCOCET. It is also not	[TRADENAME]. It is also not		
known whether PERCOCET	known whether [TRADENAME]		
can cause fetal harm when	can cause fetal harm when		
administered to a pregnant	administered to a pregnant		
woman or can affect	woman or can affect		
reproductive capacity.	reproductive capacity.		
PERCOCET should not be	[TRADENAME] should not be		Harrist Commence
given to a pregnant woman	given to a pregnant woman		
unless in the judgment of the	unless in the judgment of the		
physician, the potential benefits	physician, the potential benefits	12	2
priyatolari, the potential benefits	priyaidan, me potential benefits		<u> </u>

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outweigh the possible hazards.	outweigh the possible hazards.	-
Nonteratogenic Effects: Use	Nonteratogenic Effects: Use	
of opioids during pregnancy	of opioids during pregnancy	
may produce physical	may produce physical	
dependence in the neonate.	dependence in the neonate.	
Labor and Delivery: As with	Labor and Delivery: As with	
all opioids, administration of	all opioids, administration of	
PERCOCET to the mother	[TRADENAME] to the mother	
shortly before delivery may	shortly before delivery may	
result in some degree of	result in some degree of	
respiratory depression in the	respiratory depression in the	
newborn and the mother,	newborn and the mother,	
especially if higher doses are	especially if higher doses are	
used.	used.	
Nursing Mothers	Nursing Mothers	
It is not known whether	It is not known whether	
PERCOCET is excreted in	[TRADENAME] is excreted in	
human milk. Because many	human milk. Because many	
drugs are excreted in human	drugs are excreted in human	
milk, caution should be	milk, caution should be	
exercised when PERCOCET	exercised when	
is administered to a nursing	[TRADENAME] is	
woman.	administered to a nursing	
	woman.	
Pediatric Use	Pediatric Use	
Safety and effectiveness in	Safety and effectiveness in	
pediatric patients have not	pediatric patients have not	
been established.	been established.	
ADVERSE REACTIONS	ADVERSE REACTIONS	
The most frequently observed	The most frequently observed	
adverse reactions include	adverse reactions include	
lightheadedness, dizzness,	lightheadedness, dizziness,	
sedation, nausea and vomiting.	sedation, nausea and vomiting.	
These effects seem to be more	These effects seem to be more	
prominent in ambulatory than in	prominent in ambulatory than in	
nonambulatory patients, and	nonambulatory patients, and	
some of these adverse	some of these adverse	
reactions may be alleviated if	reactions may be alleviated if	
the patient lies down.	the patient lies down.	
Other adverse reactions	Other adverse reactions	
include euphoria, dysphoria,	include euphoria, dysphoria,	
constipation, skin rash and	constipation, skin rash and	
pruritus. At higher doses,	pruritus. At higher doses,	
oxycodone has most of the	oxycodone has most of the	
disadvantages of morphine	disadvantages of morphine	
includina respiratory	including respiratory	
depression.	depression.	
DRUG ABUSE AND	DRUG ABUSE AND	
DEPENDENCE	DEPENDENCE	
PERCOCET (Oxycodone and	[TRADENAME] (Oxycodone	
Acetaminophen Tablets, USP)	and Acetaminophen Tablets,	
is a Schedule II controlled	USP) is a Schedule II	
substance.	controlled substance.	

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Oxycodone can produce drug dependence and has the Potential for being abused	Oxycodone can produce drug dependence and has the potential for being abused	
(See WARNINGS).	(See WARNINGS). OVERDOSAGE	
OVERDOSAGE		
Acetaminophen Signs and Symptoms: In	Acetaminophen Signs and Symptoms: In	
acute acetaminophen	acute acetaminophen	
overdosage, dose-dependent,	overdosage, dose-dependent,	
potentially fatal hepatic	potentially fatal hepatic	
necrosis is the most serious	necrosis is the most serious	
adverse effect. Renal tubular	adverse effect. Renal tubular	
necrosis, hypoglycemic coma	necrosis, hypoglycemic coma	
and thrombocytopenia may	and thrombocytopenia may	
also occur.	also occur.	
The state of the s		
In adults, hepatic toxicity has	In adults, hepatic toxicity has	
rarely been reported with	rarely been reported with	
acute overdoses of less than	acute overdoses of less than	
10 grams and fatalities with	10 grams and fatalities with	
less than 15 grams.	less than 15 grams.	
Importantly, young children	Importantly, young children	
seem to be more resistant	seem to be more resistant	
than adults to the hepatotoxic	than adults to the hepatotoxic	
effect of an acetaminophen	effect of an acetaminophen	
overdose. Despite this, the	overdose. Despite this, the	
measures outlined below	measures outlined below	
should be initiated in any adult	should be initiated in any adult	
or child suspected of having	or child suspected of having	
ingested an acetaminophen	ingested an acetaminophen	
overdose.	overdose.	•
Early symptoms following a	Early symptoms following a	
potentially hepatotoxic	potentially hepatotoxic	
overdose may include: nausea,	overdose may include: nausea,	
vomiting, diaphoresis and	vomiting, diaphoresis and	
general malaise. Clinical and	general malaise. Clinical and	
laboratory evidence of hepatic	laboratory evidence of hepatic	
toxicity may not be apparent	toxicity may not be apparent	
until 48 to 72 hours post-	until 48 to 72 hours post-	
ingestion.	ingestion.	
Treatment: The stomach	Treatment: The stomach	The second secon
should be emptied promptly by	should be emptied promptly by	
lavage or by induction of	lavage or by induction of	
emesis with syrup of ipecac.	emesis with syrup of ipecac.	
Patient's estimates of the	Patient's estimates of the	
quantity of a drug ingested are	quantity of a drug ingested are	
notoriously unreliable.	notoriously unreliable.	
Therefore, if an acetaminophen	Therefore, if an acetaminophen	
overdose is suspected, a	overdose is suspected, a	
serum acetaminophen assay	serum acetaminophen assay	
should be obtained as early as	should be obtained as early as	
possible, but no sooner than	possible, but no sooner than	
four hours following ingestion.	four hours following ingestion.	
Liver function studies should be	function studies should b	
LITTE IN TOTAL STATE OF THE STA		<u>l</u>

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obtained initially and repeated	obtained initially and repeated	
at 24-hour intervals.	at 24-hour intervals.	
The antidote, N-acetylcysteine,	The antidote, N-acetylcysteine,	
should be administered as	should be administered as	
early as possible, preferably	early as possible, preferably	
within 16 hours of the overdose	within 16 hours of the overdose	
ingestion for optimal results,	ingestion for optimal results,	
but in any case, within 24	but in any case, within 24	
hours. Following recovery,	hours. Following recovery,	
there are no residual,	there are no residual,	
structural, or functional hepatic	structural, or functional hepatic	
abnormalities.	abnormalities.	
Oxycodone	Oxycodone	
Signs and Symptoms:	Signs and Symptoms:	
Serious overdosage with	Serious overdosage with	
oxycodone is characterized by	oxycodone is characterized by	
respiratory depression (a	respiratory depression (a	
decrease in respiratory rate	decrease in respiratory rate	
and/or tidal volume, Cheyne-		
	and/or tidal volume, Cheyne-	
Stokes respiration, cyanosis), extreme somnolence	Stokes respiration, cyanosis),	
and the state of t	extreme somnolence	
progressing to stupor or coma,	progressing to stupor or coma,	
skeletal muscle flaccidity, cold	skeletal muscle flaccidity, cold	
and clammy skin, and	and clammy skin, and	
sometimes bradycardia and	sometimes bradycardia and	
hypotension. In severe	hypotension. In severe	
overdosage, apnea, circulatory	overdosage, apnea, circulatory	
collapse, cardiac arrest and	collapse, cardiac arrest and	
death may occur.	death may occur.	
Treatment: Primary attention	Treatment: Primary attention	
should be given to the	should be given to the	
reestablishment of adequate	reestablishment of adequate	
respiratory exchange through	respiratory exchange through	
provision of a patent airway	provision of a patent airway	
and the institution of assisted	and the institution of assisted	
or controlled ventilation. The	or controlled ventilation. The	
opioid antagonist naloxone	opioid antagonist naloxone	
nydrochloride is a specific	hydrochloride is a specific	
antidote against respiratory	antidote against respiratory	
depression which may result	depression which may result	
from overdosage or unusual	from overdosage or unusual	
sensitivity to opioids, including	sensitivity to opioids, including	
oxycodone. Therefore, an	oxycodone. Therefore, an	
appropriate dose of naloxone	appropriate dose of naloxone	
hydrochloride (usual initial adult	hydrochloride (usual initial adult	
dose 0.4 mg to 2 mg) should	dose 0.4 mg to 2 mg) should	
be administered preferably by	be administered preferably by	
the intravenous route, and		
	the intravenous route, and	
simultaneously with efforts at	simultaneously with efforts at	
respiratory resuscitation (see	respiratory resuscitation (see	
package insert). Since the	package insert). Since the	
duration of action of oxycodone	duration of action of oxycodone	
may exceed that of the	may exceed that of the	
antagonist, the patient should	antagonist, the patient should	

The state of the s		
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be kept under continued	be kept under continued	
surveillance and repeated	surveillance and repeated	
doses of the antagonist should	doses of the antagonist should	
be administered as needed to	be administered as needed to	
maintain adequate respiration.	maintain adequate respiration.	
An antagonist should not be	An antagonist should not be	
administered in the absence of	administered in the absence of	
- 1	clinically significant respiratory	
clinically significant respiratory	1	
or cardiovascular depression.	or cardiovascular depression.	
Oxygen, intravenousfluids,	Oxygen, intravenous fluids,	
vasopressors and other	vasopressors and other	
supportive measures should	supportive measures should	
be employed as indicated.	be employed as indicated.	
Gastric emptying may be useful	Gastric emptying may be useful	
in removing unabsorbed drug.	in removing unabsorbed drug.	
DOSAGE AND	DOSAGEAND	
ADMINISTRATION	ADMINISTRATION	
Dosage should be adjusted	Dosage should be adjusted	
according to the severity of the	according to the severity of the	
pain and the response of the	pain and the response of the	
patient. It may occasionally be	patient. It may occasionally be	
necessary to exceed the usual	necessary to exceed the usual	
dosage recommended below	dosage recommended below	
in cases of more severe pain	in cases of more severe pain	
or in those patients who have	or in those patients who have	
become tolerant to the	become tolerant to the	
analgesic effect of opioids.	analgesic effect of opioids.	
PERCOCET (Oxycodone and	[TRADENAME] (Oxycodone	
Acetaminophen Tablets, USP)	and Acetaminophen Tablets,	
is given orally. The usual adult	USP) is given orally. The usual	
dosage is one tablet every 6	adult dosage is one tablet	
hours as needed for pain. The	every 6 hours as needed for	
total daily dose of	pain. The total daily dose of	
1 -		Change maximal daily dose
acetaminophen should not	acetaminophen should not	for the 15/325 mg strength to 4
exceed 4 grams (maximal	exceed 4 grams (maximal	tablets.
daily dose of PERCOCET 7.5	daily dose of [TRADENAME]	Change maximal daily dose
mg/325 mg and PERCOCET	15 mg/325 mg and	for the 20/325 mg strength to 3
10 mg/325 mg is 8 tablets and	[TRADENAME] 20 mg/325 mg	tablets.
6 tablets, respectively).	is 4 tablets and 3 tablets,	
LIGHT ON DRIVED	respectively).	
HOW SUPPLIED	HOW SUPPLIED	
PERCOCET (Oxycodone and	[TRADENAME] (Oxycodone	
Acetaminophen Tablets, USP)	and Acetaminophen Tablets,	
is supplied'asfollows:	USP) is supplied as follows:	
7.5 mg/325 mg	15 mg/325 mg	Color and description of tablet
Peach oval-shaped tablet		TBD
debossed with "PERCOCET"		
on one side and "7.5/325" on		
the other.		
Bottles of 100	Bottles of XXX	Package sizes and NDC TBD
NDC 63481-628-70	NDC XXXXX-XXX-XX	_
Bottles of 500		
NDC 63481-628-85	e e e	
	the second contract of	and the second second

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Unit dose package of 100 tablets NDC 63481-628-75		
10 mg/325 mg Yellow capsule-shaped tablet debossed with "PERCOCET" on one side and "10/325" on the other.	20 mg/325 mg	Color and description of tablet TBD
Bottles of 100 NDC 63481-629-70	Bottles of XXX NDC XXXXXX-XXX-XX	Package sizes and NDC TBD
Bottles of 500 NDC 63481-629-85		
Unit dose package of 100 tablets NDC 63481-629-75		
Store at controlled room temperature, 15" to 30°C (59" to 86°F) [see USP].	Store at 25°C (77°F), excursions permitted to 15°- 30°C (59°-86°F). [See USP Controlled Room Temperature].	Storage condition updated to be compliant with the FDA Modernization Act
Dispense in a tight, light- resistant container as defined in the USP, with a child- resistant closure (as required).	Dispense in a tight, light- resistant container as defined in the USP, with a child- resistant closure (as required).	
DEA Order Form Required.	DEA Order Form Required.	
Manufactured for: Endo Pharmaceuticals Inc. Chadds Ford, Pennsylvania 19317	Manufactured for:	
PERCOCET® is a Registered Trademark of Endo Pharmaceuticals Inc.	[TRADENAME]® is a Registered Trademark of xxxx	
Copyright © Endo Pharmaceuticals Inc. 2002	Copyright© 2002 xxxx	te copyright to 2002
Printed in U.S.A.	Printed in U.S.A.	
411042 February, 2002	XXXXXX Month, 2002	Item number and plate code TBD

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