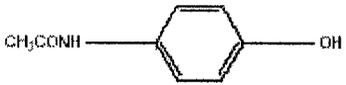
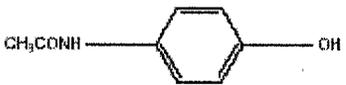
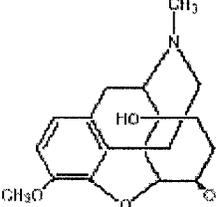
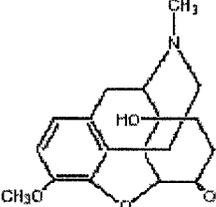


Reference Outsert PERCOCET 2.5/325 mg and 5/325 mg,(ANDA 40-330)	Proposed Outsert [TRADENAME] 2.5/325 mg and 5/325 mg Orally Disintegrating Tablets	Comments
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PERCOCET[®] (Oxycodone and Acetaminophen Tablets, USP)	[TRADENAME] (Oxycodone and Acetaminophen, USP) Orally Disintegrating Tablets	Changed PERCOCET [®] to [TRADENAME]. Added Orally Disintegrating Tablets
2.5/325 mg and 5/325 mg	2.5/325 mg and 5/325 mg	
		
R_x only	R_x only	
DESCRIPTION	DESCRIPTION	
Each tablet, for oral administration, contains oxycodone hydrochloride and acetaminophen in the following strengths:	Each orally disintegrating tablet, for oral administration, contains oxycodone hydrochloride and acetaminophen in the following strengths:	Added Orally Disintegrating.
Oxycodone Hydrochloride 2.5 mg Acetaminophen, USP 325 mg	Oxycodone Hydrochloride, USP 2.5 mg Acetaminophen, USP 325 mg	Added USP
2.5 mg oxycodone HCl is equivalent to 2.2409 mg of oxycodone.	2.5 mg oxycodone HCl is equivalent to 2.2409 mg of oxycodone.	
Oxycodone Hydrochloride 5 mg Acetaminophen, USP 325 mg	Oxycodone Hydrochloride ,USP 5 mg Acetaminophen, USP 325 mg	Added USP
5 mg oxycodone HCl is equivalent to 4.4815 mg of oxycodone.	5 mg oxycodone HCl is equivalent to 4.4815 mg of oxycodone.	
All strengths of PERCOCET also contain the following inactive ingredients: Colloidal silicon dioxide, croscarmellose sodium, crospovidone, microcrystalline cellulose, povidone, pregelatinized starch, and stearic acid. In addition, the 2.5 mg/325 mg strength contains FD&C Red No. 40 Aluminum Lake and the 5 mg/325 mg strength contains FD&C Blue No. 1 Aluminum Lake.	All strengths of [TRADENAME] Orally Disintegrating Tablets also contain the following inactive ingredients: Aspartame powder, NF, crospovidone, USP, hydroxypropyl methyl cellulose, USP, magnesium stearate, NF, mannitol, USP, methacrylic acid copolymer, microcrystalline cellulose, USP, peppermint flavor, silicon dioxide, NF. In addition, the 2.5 mg/325 mg strength contains FD&C Red No.	Changed PERCOCET [®] to [TRADENAME] Orally Disintegrating Tablets. Changed inactive ingredients to match [TRADENAME] ingredients.

Reference Outsert PERCOCET 2.5/325 mg and 5/325 mg,(ANDA 40-330)	Proposed Outsert [TRADENAME] 2.5/325 mg and 5/325 mg Orally Disintegrating Tablets	Comments
	40 Aluminum Lake and the 5 mg/325 mg strength contains FD&C Blue No. 1 Aluminum Lake.	
Acetaminophen, 4'-hydroxyacetanilide, is a non-opiate, non-salicylate analgesic and antipyretic which occurs as a white, odorless, crystalline powder, possessing a slightly bitter taste. The molecular formula for acetaminophen is C ₈ H ₉ NO ₂ and the molecular weight is 151.17. It may be represented by the following structural formula:	Acetaminophen, 4'-hydroxyacetanilide, is a non-opiate, non-salicylate analgesic and antipyretic which occurs as a white, odorless, crystalline powder, possessing a slightly bitter taste. The molecular formula for acetaminophen is C ₈ H ₉ NO ₂ and the molecular weight is 151.17. It may be represented by the following structural formula:	
		
Oxycodone, 14-hydroxydihydrocodeinone, is a semisynthetic pure opioid agonist which occurs as a white, odorless, crystalline powder having a saline, bitter taste. The molecular formula for oxycodone hydrochloride is C ₁₈ H ₂₁ NO ₄ • HCl and the molecular weight is 351.83. It is derived from the opium alkaloid thebaine, and may be represented by the following structural formula:	Oxycodone, 14-hydroxydihydrocodeinone, is a semisynthetic pure opioid agonist which occurs as a white, odorless, crystalline powder having a saline, bitter taste. The molecular formula for oxycodone hydrochloride is C ₁₈ H ₂₁ NO ₄ • HCl and the molecular weight is 351.83. It is derived from the opium alkaloid thebaine, and may be represented by the following structural formula:	
		
CLINICAL PHARMACOLOGY	CLINICAL PHARMACOLOGY	
The principal ingredient,	The principal ingredient,	

Reference Outsert PERCOCET 2.5/325 mg and 5/325 mg,(ANDA 40-330)	Proposed Outsert [TRADENAME] 2.5/325 mg and 5/325 mg Orally Disintegrating Tablets	Comments
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oxycodone, is a semisynthetic opioid analgesic with multiple actions qualitatively similar to those of morphine; the most prominent involves the central nervous system and organs composed of smooth muscle. The principal actions of therapeutic value of the oxycodone in PERCOCET are analgesia and sedation.	oxycodone, is a semisynthetic opioid analgesic with multiple actions qualitatively similar to those of morphine; the most prominent involves the central nervous system and organs composed of smooth muscle. The principal actions of therapeutic value of the oxycodone in [TRADENAME] Orally Disintegrating Tablets are analgesic and sedation.	Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets.
Oxycodone is similar to codeine and methadone in that it retains at least one-half of its analgesic activity when administered orally.	Oxycodone is similar to codeine and methadone in that it retains at least one-half of its analgesic activity when administered orally.	
Acetaminophen is a non-opiate, non-salicylate analgesic and antipyretic.	Acetaminophen is a non-opiate, non-salicylate analgesic and antipyretic.	
INDICATIONS AND USAGE	INDICATIONS AND USAGE	
PERCOCET is indicated for the relief of moderate to moderately severe pain.	[TRADENAME] Orally Disintegrating Tablets are indicated for the relief of moderate to moderately severe pain.	Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets.
CONTRAINDICATIONS	CONTRAINDICATIONS	
PERCOCET should not be administered to patients who are hypersensitive to oxycodone, acetaminophen, or any other components of this product.	[TRADENAME] Orally Disintegrating Tablets should not be administered to patients who are hypersensitive to oxycodone, acetaminophen, or any other components of this product.	Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets.
WARNINGS	WARNINGS	
Drug Dependence	Drug Dependence	
Oxycodone can produce drug dependence of the morphine type and, therefore, has the potential for being abused. Psychic dependence, physical dependence	Oxycodone can produce drug dependence of the morphine type and, therefore, has the potential for being abused. Psychic dependence, physical dependence	

Reference Outsert PERCOCET 2.5/325 mg and 5/325 mg,(ANDA 40-330)	Proposed Outsert [TRADENAME] 2.5/325 mg and 5/325 mg Orally Disintegrating Tablets	Comments
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<p>and tolerance may develop upon repeated administration of PERCOCET, and it should be prescribed and administered with the same degree of caution appropriate to the use of other oral opioid-containing medications. Like other opioid-containing medications, PERCOCET is subject to the Federal Controlled Substances Act (Schedule II).</p>	<p>and tolerance may develop upon repeated administration of [TRADENAME] Orally Disintegrating Tablets, and it should be prescribed and administered with the same degree of caution appropriate to the use of other oral opioid-containing medications. Like other opioid-containing medications, [TRADENAME] Orally Disintegrating Tablets are subject to the Federal Controlled Substance Act (Schedule II).</p>	<p>Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets.</p> <p>Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets.</p>
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PRECAUTIONS	PRECAUTIONS	
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General	General	
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<p>Head Injury and Increased Intracranial Pressure: The respiratory depressant effects of opioids and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a pre-existing increase in intracranial pressure. Furthermore, opioids produce adverse reactions which may obscure the clinical course of patients with head injuries.</p>	<p>Head Injury and Increased Intracranial Pressure: The respiratory depressant effects of opioids and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a pre-existing increase in intracranial pressure. Furthermore, opioids produce adverse reactions which may obscure the clinical course of patients with head injuries.</p>	
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<p>Acute Abdominal Conditions: The administration of PERCOCET (Oxycodone and Acetaminophen Tablets, USP) or other opioids may obscure the diagnosis or clinical course in patients with acute abdominal conditions.</p>	<p>Acute Abdominal Conditions: The administration of [TRADENAME] (Oxycodone and Acetaminophen, USP) Orally Disintegrating Tablets or other opioids may obscure the diagnosis or clinical course in patients with acute abdominal conditions.</p>	<p>Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets.</p>
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Reference Outsert PERCOCET 2.5/325 mg and 5/325 mg,(ANDA 40-330)	Proposed Outsert [TRADENAME] 2.5/325 mg and 5/325 mg Orally Disintegrating Tablets	Comments
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<p>Special Risk Patients: PERCOCET should be given with caution to certain patients such as the elderly or debilitated, and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, and prostatic hypertrophy or urethral stricture.</p>	<p>Special Risk Patients: [TRADENAME] Orally Disintegrating Tablets should be given with caution to certain patients such as the elderly or debilitated, and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, and prostatic hypertrophy or urethral stricture.</p>	<p>Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets.</p>
<p>Information for Patients</p>	<p>Information for Patients</p>	
<p>Oxycodone may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. The patient using PERCOCET should be cautioned accordingly.</p>	<p>Oxycodone may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. The patient using [TRADENAME] Orally Disintegrating Tablets should be cautioned accordingly.</p>	<p>Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets.</p>
	<p>Patients should be instructed to not remove [TRADENAME] Orally Disintegrating Tablets from the blister until just prior to dosing. The tablet should not be pushed through the foil. Immediately upon opening the blister, using dry hands, remove the tablet and place it in the mouth. Tablet disintegration occurs rapidly in saliva so it can be easily swallowed with or without water.</p>	<p>Text added to instruct patients on proper handling techniques and dosing.</p>
<p>Drug Interactions</p>	<p>Drug Interactions</p>	
<p>Patients receiving other opioid analgesics, general anesthetics, phenothiazines, other tranquilizers, sedative-hypnotics or other CNS depressants (including alcohol) concomitantly with PERCOCET may exhibit an additive CNS depression. When such combined therapy is</p>	<p>Patients receiving other opioid analgesics, general anesthetics, phenothiazines, other tranquilizers, sedative-hypnotics or other CNS depressants (including alcohol) concomitantly with [TRADENAME] Orally Disintegrating Tablets may exhibit an additive CNS</p>	<p>Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets.</p>

Reference Outsert PERCOCET 2.5/325 mg and 5/325 mg,(ANDA 40-330)	Proposed Outsert [TRADENAME] 2.5/325 mg and 5/325 mg Orally Disintegrating Tablets	Comments
contemplated, the dose of one or both agents should be reduced.	depression. When such combined therapy is contemplated, the dose of one or both agents should be reduced.	
The concurrent use of anticholinergics with opioids may produce paralytic ileus.	The concurrent use of anticholinergics with opioids may produce paralytic ileus.	
Usage in Pregnancy	Usage in Pregnancy	
Teratogenic Effects; Pregnancy Category C: Animal reproductive studies have not been conducted with PERCOCET. It is also not known whether PERCOCET can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. PERCOCET should not be given to a pregnant woman unless in the judgment of the physician, the potential benefits outweigh the possible hazards.	Teratogenic Effects; Pregnancy Category C: Animal reproductive studies have not been conducted with [TRADENAME] Orally Disintegrating Tablets. It is also not known whether [TRADENAME] Orally Disintegrating Tablets can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. [TRADENAME] Orally Disintegrating Tablets should not be given to a pregnant woman unless in the judgment of the physician, the potential benefits outweigh the possible hazards.	Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets. Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets. Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets.
Nonteratogenic Effects: Use of opioids during pregnancy may produce physical dependence in the neonate.	Nonteratogenic Effects: Use of opioids during pregnancy may produce physical dependence in the neonate.	
Labor and Delivery: As with all opioids, administration of PERCOCET to the mother shortly before delivery may result in some degree of respiratory depression in the newborn and the mother, especially if higher doses are used.	Labor and Delivery: As with all opioids, administration of [TRADENAME] Orally Disintegrating Tablets to the mother shortly before delivery may result in some degree of respiratory depression in the newborn and the mother, especially if higher doses are used.	Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets.
Nursing Mothers	Nursing Mothers	
It is not known whether PERCOCET is excreted in human	It is not known whether [TRADENAME] Orally	Changed PERCOCET® to

Reference Outsert PERCOCET 2.5/325 mg and 5/325 mg,(ANDA 40-330)	Proposed Outsert [TRADENAME] 2.5/325 mg and 5/325 mg Orally Disintegrating Tablets	Comments
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milk. Because many drugs are excreted in human milk, caution should be exercised when PERCOCET is administered to a nursing woman.	Disintegrating Tablets is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when [TRADENAME] Orally Disintegrating Tablets is administered to a nursing woman.	[TRADENAME] Orally Disintegrating Tablets. Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets.
Pediatric Use	Pediatric Use	
Safety and effectiveness in pediatric patients have not been established.	Safety and effectiveness in pediatric patients have not been established.	
ADVERSE REACTIONS	ADVERSE REACTIONS	
The most frequently observed adverse reactions include lightheadedness, dizziness, sedation, nausea and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down.	The most frequently observed adverse reactions include lightheadedness, dizziness, sedation, nausea and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down.	
Other adverse reactions include euphoria, dysphoria, constipation, skin rash and pruritus. At higher doses, oxycodone has most of the disadvantages of morphine including respiratory depression.	Other adverse reactions include euphoria, dysphoria, constipation, skin rash and pruritus. At higher doses, oxycodone has most of the disadvantages of morphine including respiratory distress.	
DRUG ABUSE AND DEPENDENCE	DRUG ABUSE AND DEPENDENCE	
PERCOCET (Oxycodone and Acetaminophen Tablets, USP) is a Schedule II controlled substance.	[TRADENAME] (Oxycodone and Acetaminophen, USP) Orally Disintegrating Tablets are a Schedule II controlled substance.	Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets.
Oxycodone can produce drug dependence and has the potential for being abused (See WARNINGS).	Oxycodone can produce drug dependence and has the potential for being abused (See WARNINGS).	
OVERDOSAGE	OVERDOSAGE	
Acetaminophen	Acetaminophen	

Reference Outsert PERCOCET 2.5/325 mg and 5/325 mg,(ANDA 40-330)	Proposed Outsert [TRADENAME] 2.5/325 mg and 5/325 mg Orally Disintegrating Tablets	Comments
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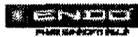
<p>Signs and Symptoms: In acute acetaminophen overdose, dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma and thrombocytopenia may also occur.</p>	<p>Signs and Symptoms: In acute acetaminophen overdose, dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma and thrombocytopenia may also occur.</p>	
<p>In adults, hepatic toxicity has rarely been reported with acute overdoses of less than 10 grams and fatalities with less than 15 grams. Importantly, young children seem to be more resistant than adults to the hepatotoxic effect of an acetaminophen overdose. Despite this, the measures outlined below should be initiated in any adult or child suspected of having ingested an acetaminophen overdose.</p>	<p>In adults, hepatic toxicity has rarely been reported with acute overdoses of less than 10 grams and fatalities with less than 15 grams. Importantly, young children seem to be more resistant than adults to the hepatotoxic effect of an acetaminophen overdose. Despite this, the measures outlined below should be initiated in any adult or child suspected of having ingested an acetaminophen overdose.</p>	
<p>Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion.</p>	<p>Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion.</p>	
<p>Treatment: The stomach should be emptied promptly by lavage or by induction of emesis with syrup of ipecac. Patient's estimates of the quantity of a drug ingested are notoriously unreliable. Therefore, if an acetaminophen overdose is suspected, a serum acetaminophen assay should be obtained as early as possible, but no sooner than four hours following ingestion. Liver function studies should be</p>	<p>Treatment: The stomach should be emptied promptly by lavage or by induction of emesis with syrup of ipecac. Patient's estimates of the quantity of a drug ingestions are notoriously unreliable. Therefore, if an acetaminophen overdose is suspected, a serum acetaminophen assay should be obtained as early as possible, but no sooner than four hours following ingestion. Liver function studies should be</p>	

Reference Outsert PERCOCET 2.5/325 mg and 5/325 mg,(ANDA 40-330)	Proposed Outsert [TRADENAME] 2.5/325 mg and 5/325 mg Orally Disintegrating Tablets	Comments
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obtained initially and repeated at 24-hour intervals.	obtained initially and repeated at 24-hour intervals.	
The antidote, N-acetylcysteine, should be administered as early as possible, preferably within 16 hours of the overdose ingestion for optimal results, but in any case, within 24 hours. Following recovery, there are no residual, structural, or functional hepatic abnormalities.	The antidote, N-acetylcysteine, should be administered as early as possible, preferably within 16 hours of the overdose ingestion for optimal results, but in any case, within 24 hours. Following recovery, there are no residual, structural, or functional hepatic abnormalities.	
Oxycodone	Oxycodone	
Signs and Symptoms: Serious overdosage with oxycodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur.	Signs and Symptoms: Serious overdosage with oxycodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur.	
Treatment: Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The opioid antagonist naloxone hydrochloride is a specific antidote against respiratory depression which may result from overdosage or unusual sensitivity to opioids, including oxycodone. Therefore, an appropriate dose of naloxone hydrochloride (usual initial adult dose 0.4 mg to 2 mg)	Treatment: Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The opioid antagonist naloxone hydrochloride is a specific antidote against respiratory depression which may result from overdosage or unusual sensitivity to opioids, including oxycodone. Therefore, an appropriate dose of naloxone hydrochloride (usual initial adult dose 0.4 mg to 2 mg)	

Reference Outsert PERCOCET 2.5/325 mg and 5/325 mg,(ANDA 40-330)	Proposed Outsert [TRADENAME] 2.5/325 mg and 5/325 mg Orally Disintegrating Tablets	Comments
<p>should be administered preferably by the intravenous route, and simultaneously with efforts at respiratory resuscitation (see package insert). Since the duration of action of oxycodone may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration.</p>	<p>should be administered preferably by the intravenous route, and simultaneously with efforts at respiratory resuscitation (see package insert). Since the duration of action of oxycodone may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration.</p>	
<p>An antagonist should not be administered in the absence of clinically significant respiratory or cardiovascular depression. Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated.</p>	<p>An antagonist should not be administered in the absence of clinically significant respiratory or cardiovascular depression. Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated.</p>	
<p>Gastric emptying may be useful in removing unabsorbed drug.</p>	<p>Gastric emptying may be useful in removing unabsorbed drug.</p>	
<p>DOSAGE AND ADMINISTRATION</p>	<p>DOSAGE AND ADMINISTRATION</p>	
<p>Dosage should be adjusted according to the severity of the pain and the response of the patient. It may occasionally be necessary to exceed the usual dosage recommended below in cases of more severe pain or in those patients who have become tolerant to the analgesic effect of opioids. PERCOCET (Oxycodone and Acetaminophen Tablets, USP) is given orally.</p>	<p>Dosage should be adjusted according to the severity of the pain and the response of the patient. It may occasionally be necessary to exceed the usual dosage recommended below in cases of more severe pain or in those patients who have become tolerant to the analgesic effect of opioids.</p>	<p>The last sentence in this paragraph has been moved to the paragraph below.</p>
	<p>[TRADENAME] (Oxycodone and Acetaminophen, USP) Orally Disintegrating Tablets are given orally. Just prior to dosing, peel back the foil on the blister. Do</p>	<p>Text added to instruct patients on proper handling techniques and dosing.</p>

Reference Outsert PERCOCET 2.5/325 mg and 5/325 mg,(ANDA 40-330)	Proposed Outsert [TRADENAME] 2.5/325 mg and 5/325 mg Orally Disintegrating Tablets	Comments																
	not push the tablet through the foil. Immediately upon opening the blister using dry hands, remove the tablet and place it in the mouth. Tablet disintegration occurs rapidly in saliva so it can be easily swallowed with or without water.																	
Percocet 2.5 mg/325 mg The usual adult dosage is one or two tablets every six hours. The total daily dose of acetaminophen should not exceed 4 grams.	[TRADENAME] Orally Disintegrating Tablets 2.5 mg/325 mg The usual adult dosage is one or two orally disintegrating tablets every six hours. The total daily dose of acetaminophen should not exceed 4 grams.	Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets. Added “orally disintegrating”																
Percocet 5 mg/325 mg The usual adult dosage is one tablet every 6 hours as needed for pain. The total daily dose of acetaminophen should not exceed 4 grams.	[TRADENAME] Orally Disintegrating Tablets 5 mg/325 mg The usual adult dosage is one orally disintegrating tablet every 6 hours as needed for pain. The total daily dose of acetaminophen should not exceed 4.	Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets. Added “orally disintegrating”																
<table border="0"> <thead> <tr> <th data-bbox="167 1208 381 1244">Strength</th> <th data-bbox="381 1208 638 1244">Maximal Daily Dose</th> </tr> </thead> <tbody> <tr> <td data-bbox="167 1272 381 1308">Percocet 2.5 mg/325 mg</td> <td data-bbox="381 1272 638 1308">12 Tablets</td> </tr> <tr> <td data-bbox="167 1351 381 1387">Percocet 5 mg/325 mg</td> <td data-bbox="381 1351 638 1387">12 Tablets</td> </tr> </tbody> </table>	Strength	Maximal Daily Dose	Percocet 2.5 mg/325 mg	12 Tablets	Percocet 5 mg/325 mg	12 Tablets	<table border="0"> <thead> <tr> <th data-bbox="638 1208 852 1244">Strength</th> <th data-bbox="852 1208 1109 1244">Maximal Daily Dose</th> </tr> </thead> <tbody> <tr> <td data-bbox="638 1272 852 1308">[TRADENAME] Orally Disintegrating Tablets</td> <td data-bbox="852 1272 1109 1308"></td> </tr> <tr> <td data-bbox="638 1351 852 1387">2.5 mg/325 mg</td> <td data-bbox="852 1351 1109 1387">12 Tablets</td> </tr> <tr> <td data-bbox="638 1387 852 1423">[TRADENAME] Orally Disintegrating Tablets</td> <td data-bbox="852 1387 1109 1423"></td> </tr> <tr> <td data-bbox="638 1466 852 1502">5 mg/325 mg</td> <td data-bbox="852 1466 1109 1502">12 Tablets</td> </tr> </tbody> </table>	Strength	Maximal Daily Dose	[TRADENAME] Orally Disintegrating Tablets		2.5 mg/325 mg	12 Tablets	[TRADENAME] Orally Disintegrating Tablets		5 mg/325 mg	12 Tablets	Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets. Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets.
Strength	Maximal Daily Dose																	
Percocet 2.5 mg/325 mg	12 Tablets																	
Percocet 5 mg/325 mg	12 Tablets																	
Strength	Maximal Daily Dose																	
[TRADENAME] Orally Disintegrating Tablets																		
2.5 mg/325 mg	12 Tablets																	
[TRADENAME] Orally Disintegrating Tablets																		
5 mg/325 mg	12 Tablets																	
HOW SUPPLIED	HOW SUPPLIED																	
PERCOCET (Oxycodone and Acetaminophen Tablets, USP) are supplied as follows:	[TRADENAME] (Oxycodone and Acetaminophen, USP) Orally Disintegrating Tablets are supplied as follows:	Changed PERCOCET® to [TRADENAME] Orally Disintegrating Tablets.																
2.5 mg/325 mg Pink oval tablet embossed with “PERCOCET” on one side and “2.5” on the other.	2.5 mg/325 mg Tablet description to be determined.																	

Reference Outsert PERCOCET 2.5/325 mg and 5/325 mg,(ANDA 40-330)	Proposed Outsert [TRADENAME] 2.5/325 mg and 5/325 mg Orally Disintegrating Tablets	Comments
Bottles of 100 NDC 63481-627-70 Bottles of 500 NDC 63481-627-85		
Unit dose package of 100 tablets NDC 63481-627-75	Unit dose package of xxx tablets NDC xxxxx-xxx-xx	NDC numbers to be assigned at a later date.
5 mg/325 mg Blue, round, tablet, embossed with "PERCOCET" and "5" on one side and bisect on the other. Bottles of 100 NDC 63481-623-70 Bottles of 500 NDC 63481-623-85	5 mg/325 mg Tablet description to be determined.	
Unit dose package of 100 tablets NDC 63481-623-75	Unit dose package of xxx tablets NDC xxxxx-xxx-xx	NDC numbers to be assigned at a later date.
Store at 25°C (77°F); excursions permitted to 15°-30°C (59°- 86°F).[See USP Controlled Room Temperature.]	Store at 25°C (77°F); excursions permitted to 15°-30°C (59°- 86°F). [See USP Controlled Room Temperature.]	
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		
		
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