

F A C T S H E E T

Endocet[®] Tablets (Oxycodone and Acetaminophen Tablets, USP) 7.5 mg/500 mg



Endocet[®] Tablets (Oxycodone and Acetaminophen Tablets, USP) 10 mg/650 mg



Generic equivalent to Percocet[®] 7.5 mg/500 mg Tablets and Percocet[®] 10 mg/650 mg Tablets

Endocet[®] 7.5 mg/500 mg Tablets and Endocet[®] 10 mg/650 mg Tablets

Item # 60951-	Product Description	Count	Color/ID			
0796-70	7.5 mg/500 mg Tablets	100	PEACH CAPSULE-SHAPED TABLET WITH E 796 ON ONE SIDE AND 7.5 ON THE OTHER.			
0797-70	10 mg/650 mg Tablets	100	YELLOW OVAL TABLET WITH E 797 ON ONE SIDE AND 10 ON THE OTHER.			
	Bottle Size	Volume	Weight	Height	Length	Depth
0796-70	100 Tablets	21.52 cu. in.	0.25 lbs.	4.25"	N.A.	2.25"
0797-70	100 Tablets	21.52 cu. in.	0.31 lbs.	4.25"	N.A.	2.25"
Inner Pack	Count	Volume	Weight	Height	Length	Depth
0796-70	6	133.88 cu. in.	1.50 lbs.	4.50"	7.00"	4.25"
0797-70	6	133.88 cu. in.	1.88 lbs.	4.50"	7.00"	4.25"
Case Pack	Count	Volume	Weight	Height	Length	Depth
0796-70	48	0.67 cu. ft.	14.00 lbs.	8.75"	14.00"	9.50"
0797-70	48	0.67 cu. ft.	17.00 lbs.	8.75"	14.00"	9.50"

The most frequently reported adverse reactions are lightheadedness, dizziness, sedation, nausea, vomiting, and constipation. Oxycodone can produce drug dependence and has the potential for being abused.



Endocet[®] is a registered trademark of Endo Pharmaceuticals Inc.
Percocet[®] is a registered trademark of Endo Pharmaceuticals Inc.

Please see Brief Summary information on following page.



ENDOCET®

(Oxycodone and Acetaminophen Tablets, USP)

5 mg/325 mg, 7.5 mg/325 mg, 7.5 mg/500 mg,
10 mg/325 mg and 10 mg/650 mg



Brief Summary (For full Prescribing Information and Patient Information, refer to package insert.)

INDICATIONS AND USAGE

ENDOCET is indicated for the relief of moderate to moderately severe pain.

CONTRAINDICATIONS

ENDOCET should not be administered to patients who are hypersensitive to oxycodone, acetaminophen, or any other components of this product.

WARNINGS

Drug Dependence

Oxycodone can produce drug dependence of the morphine type and, therefore, has the potential for being abused. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of ENDOCET, 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, ENDOCET is subject to the Federal Controlled Substances Act (Schedule II).

PRECAUTIONS

General

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.

Acute Abdominal Conditions: The administration of ENDOCET or other opioids may obscure the diagnosis or clinical course in patients with acute abdominal conditions.

Special Risk Patients: ENDOCET 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.

Information for Patients

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 ENDOCET should be cautioned accordingly.

Drug Interactions

Patients receiving other opioid analgesics, general anesthetics, phenothiazines, other tranquilizers, sedative-hypnotics or other CNS depressants (including alcohol) concomitantly with ENDOCET may exhibit an additive CNS 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.

Usage in Pregnancy

Teratogenic Effects; Pregnancy Category C: Animal reproductive studies have not been conducted with ENDOCET. It is also not known whether ENDOCET can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. ENDOCET should not be given to a pregnant woman unless in the judgment of the physician, the potential benefits outweigh the possible hazards.

Nonteratogenic Effects: Use of opioids during pregnancy may produce physical dependence in the neonate.

Labor and Delivery

As with all opioids, administration of ENDOCET 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.

Nursing Mothers

It is not known whether ENDOCET (Oxycodone and Acetaminophen Tablets, USP) is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ENDOCET is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

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.

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.

DRUG ABUSE AND DEPENDENCE

ENDOCET (Oxycodone and Acetaminophen Tablets, USP) is a Schedule II controlled substance.

Oxycodone can produce drug dependence and has the potential for being abused (See WARNINGS).

OVERDOSAGE

Acetaminophen

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.

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.

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.

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 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.

Oxycodone

Signs and Symptoms: Serious overdose 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 overdose, 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 overdose or unusual sensitivity to opioids, including oxycodone. Therefore, an appropriate dose of naloxone hydrochloride (usual initial adult dose 0.4 mg to 2 mg) 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.

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.

Gastric emptying may be useful in removing unabsorbed drug.

DOSAGE AND ADMINISTRATION

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. ENDOCET is given orally. 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.

Strength	Maximal Daily Dose
ENDOCET 5 mg/325 mg	12 Tablets
ENDOCET 7.5 mg/325 mg	8 Tablets
ENDOCET 7.5 mg/500 mg	8 Tablets
ENDOCET 10 mg/325 mg	6 Tablets
ENDOCET 10 mg/650 mg	6 Tablets

Store at 20° to 25°C (68° to 77°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).

DEA Order Form Required.

Manufactured for:
Endo Pharmaceuticals Inc.
Chadds Ford, Pennsylvania 19317



ENDOCET® is a Registered Trademark of Endo Pharmaceuticals Inc.

Copyright © Endo Pharmaceuticals Inc. 2004

Printed in U.S.A.

Rev. October, 2004
415142/415342 E1