



PHARMACY PRODUCT ALERT

NEW EMBEDA™ (morphine sulfate and naltrexone hydrochloride) Extended Release Capsules

CONTACT YOUR WHOLESALER TO ORDER

HOW SUPPLIED

EMBEDA™						
DOSING STRENGTHS						
NDC #	60793-430-01	60793-431-01	60793-433-01	60793-434-01	60793-435-01	60793-437-01
Wholesaler Ordering Information—Item Numbers						
Wholesaler	20 mg/0.8 mg	30 mg/1.2 mg	50 mg/2 mg	60 mg/2.4 mg	80 mg/3.2 mg	100 mg/4 mg
Cardinal	4247706	4247714	4247722	4247730	4247763	4248035
McKesson	1210632	1210756	1211036	1211648	1211671	1211853
ABC	021-030	021-168	021-206	021-232	021-321	021-337
HD Smith	227-8075	227-8083	227-8091	227-8117	227-8125	227-8133
Morris & Dickson	994657	994665	994673	994681	994699	994707
Kinray	409-870	410-282	411-199	411-751	412-130	412-411
Smith Drug	40-2925	40-2206	40-1638	40-0986	40-0218	39-9543

Capsules shown are not the actual size.

PLEASE COMPLETE A DEA FORM 222 AND SEND TO YOUR WHOLESALER WHEN ORDERING EMBEDA™.

Important Safety Information

WARNING: EMBEDA™ (morphine sulfate and naltrexone hydrochloride) Extended Release Capsules contain morphine, an opioid agonist and a Schedule II controlled substance with an abuse liability similar to other opioid agonists. EMBEDA™ can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing EMBEDA™ in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

EMBEDA™ contains pellets of an extended-release oral formulation of morphine sulfate, an opioid receptor agonist, surrounding an inner core of naltrexone hydrochloride, an opioid receptor antagonist indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

EMBEDA™ is NOT intended for use as a prn analgesic.

EMBEDA™ 100 mg/4 mg IS FOR USE IN OPIOID-TOLERANT PATIENTS ONLY. Ingestion of these capsules or the pellets within the capsules may cause fatal respiratory depression when administered to patients not already tolerant to high doses of opioids.

Patients should not consume alcoholic beverages while on EMBEDA™ therapy. Additionally, patients must not use prescription or non-prescription medications containing alcohol while on EMBEDA™ therapy. The co-ingestion of alcohol with EMBEDA™ may result in an increase of plasma levels and potentially fatal overdose of morphine. EMBEDA™ is to be swallowed whole or the contents of the capsules sprinkled on apple sauce. The pellets in the capsules are not to be crushed, dissolved, or chewed due to the risk of rapid release and absorption of a potentially fatal dose of morphine.

Crushing, chewing, or dissolving EMBEDA™ will also result in the release of naltrexone which may precipitate withdrawal in opioid-tolerant individuals.

- EMBEDA™ is contraindicated in patients with a known hypersensitivity to morphine, morphine salts, naltrexone, or in any situation where opioids are contraindicated
- EMBEDA™ is contraindicated in patients with significant respiratory depression in unmonitored settings or the absence of resuscitative equipment
- EMBEDA™ is contraindicated in patients with acute or severe bronchial asthma or hypercapnia in unmonitored settings or the absence of resuscitative equipment
- EMBEDA™ is contraindicated in any patient who has or is suspected of having paralytic ileus
- EMBEDA™ may be expected to have additive effects when used in conjunction with alcohol, other opioids, or illicit drugs that cause central nervous system depression because respiratory depression, hypotension, and profound sedation or coma may result
- Respiratory depression is the chief hazard of all morphine preparations such as EMBEDA™. Respiratory depression occurs more frequently and is more dangerous in elderly and debilitated patients, and those suffering from conditions accompanied by hypoxia, hypercapnia, or upper airway obstruction (when even moderate therapeutic doses may significantly decrease pulmonary ventilation)
- EMBEDA™ should be used with extreme caution in patients with chronic obstructive pulmonary disease or cor pulmonale, and in patients having a substantially decreased respiratory reserve (e.g., severe kyphoscoliosis), hypoxia, hypercapnia, or pre-existing respiratory depression. In such patients, even usual therapeutic doses of morphine may increase airway resistance and decrease respiratory drive to the point of apnea. In these patients, alternative non-opioid analgesics should be considered, and opioids should be employed only under careful medical supervision at the lowest effective dose
- The respiratory depressant effects of morphine with carbon dioxide retention and secondary elevation of cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions, or a pre-existing increase in intracranial pressure. EMBEDA™ can produce effects on pupillary response and consciousness, which may obscure neurologic signs of further increases in pressure in patients with head injuries. EMBEDA™ should only be administered under such circumstances when considered essential and then with extreme care
- EMBEDA™ may cause severe hypotension. There is an added risk to individuals whose ability to maintain blood pressure has already been compromised by a reduced blood volume or a concurrent administration of drugs such as phenothiazines or general anesthetics. EMBEDA™ may produce orthostatic hypotension and syncope in ambulatory patients
- EMBEDA™ should be administered with caution to patients in circulatory shock, as vasodilation produced by the drug may further reduce cardiac output and blood pressure
- EMBEDA™ should be used with caution and in reduced dosage in patients who are concurrently receiving other central nervous system depressants including sedatives or hypnotics, general anesthetics, phenothiazines, other tranquilizers, and alcohol because respiratory depression, hypotension, and profound sedation or coma may result
- EMBEDA™ should not be given to patients with gastrointestinal obstruction, particularly paralytic ileus, as there is a risk of the product remaining in the stomach for an extended period and the subsequent release of a bolus of morphine when normal gut motility is restored
- Patients taking EMBEDA™ who are scheduled for cordotomy or other interruption of pain transmission pathways should have EMBEDA™ ceased 24 hours prior to the procedure and the pain controlled by parenteral short-acting opioids. In addition, the post-procedure titration of analgesics for such patients should be individualized to avoid either oversedation or withdrawal syndromes
- EMBEDA™ may cause spasm of the sphincter of Oddi and should be used with caution in patients with biliary tract disease, including acute pancreatitis
- Tolerance is the need for increasing doses of opioids to maintain a defined effect such as analgesia (in the absence of disease progression or other external factors). Physical dependence is manifested by withdrawal symptoms after abrupt discontinuation of a drug or upon administration of an antagonist. Physical dependence and tolerance are common during chronic opioid therapy
- EMBEDA™ should be administered with caution and in reduced dosages in elderly or debilitated patients; patients with severe renal or hepatic insufficiency; Addison's disease; myxedema; hypothyroidism; prostatic hypertrophy or urethral stricture
- Caution should also be exercised in the administration of EMBEDA™ to patients with CNS depression, toxic psychosis, acute alcoholism, and delirium tremens
- All opioids may aggravate convulsions in patients with convulsive disorders, and all opioids may induce or aggravate seizures in some clinical settings
- EMBEDA™ may impair the mental and/or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Patients must be cautioned accordingly. Patients should also be warned about the potential combined effects of EMBEDA™ with other CNS depressants, including other opioids, phenothiazines, sedative/hypnotics, and alcohol
- Agonist/antagonist analgesics (i.e., pentazocine, nalbuphine, butorphanol) should be administered with caution to a patient who has received or is receiving a course of therapy with EMBEDA™. In this situation, mixed agonist/antagonist analgesics may reduce the analgesic effect of EMBEDA™ and/or may precipitate withdrawal symptoms in these patients
- Consuming EMBEDA™ that has been tampered with by crushing, chewing, or dissolving the extended-release formulation can release sufficient naltrexone to precipitate withdrawal in opioid-dependent individuals. Symptoms of withdrawal usually appear within five minutes of ingestion of naltrexone and can last for up to 48 hours. Mental status changes can include confusion, somnolence, and visual hallucinations. Significant fluid losses from vomiting and diarrhea can require intravenous fluid administration. Patients should be closely monitored and therapy with non-opioid medications tailored to meet individual requirements
- Care should be taken to use low initial doses of EMBEDA™ in patients who are not already opioid-tolerant, especially those who are receiving concurrent treatment with muscle relaxants, sedatives, or other CNS active medications
- EMBEDA™ should not be abruptly discontinued
- SERIOUS adverse reactions that may be associated with EMBEDA™ therapy in clinical use include: respiratory depression, respiratory arrest, apnea, circulatory depression, cardiac arrest, hypotension, and/or shock
- The common adverse events seen on initiation of therapy with EMBEDA™ are dose dependent, and their frequency depends on the clinical setting, the patient's level of opioid tolerance, and host factors specific to the individual. They should be expected and managed as part of opioid analgesia. The most frequent of these include drowsiness, dizziness, constipation, and nausea
- Additional common adverse events reported during clinical studies include constipation, nausea, and somnolence
- EMBEDA™ should be used with great caution and in reduced dosage in patients who are concurrently receiving other central nervous system (CNS) depressants including sedatives, hypnotics, general anesthetics, antiemetics, phenothiazines, other tranquilizers, and alcohol because of the risk of respiratory depression, hypotension, and profound sedation or coma. When such combined therapy is contemplated, the initial dose of one or both agents should be reduced by at least 50%
- EMBEDA™ may enhance the neuromuscular blocking action of skeletal relaxants and produce an increased degree of respiratory depression
- Monoamine oxidase inhibitors (MAOIs) have been reported to potentiate the effects of morphine anxiety, confusion, and significant depression of respiration or coma. EMBEDA™ should not be used in patients taking MAOIs or within 14 days of stopping such treatment
- There is an isolated report of confusion and severe respiratory depression when a hemodialysis patient was concurrently administered morphine and cimetidine
- Morphine can reduce the efficacy of diuretics by inducing the release of antidiuretic hormone. Morphine may also lead to acute retention of urine by causing spasm of the sphincter of the bladder, particularly in men with prostatism
- Anticholinergics or other medications with anticholinergic activity when used concurrently with opioid analgesics may result in increased risk of urinary retention and/or severe constipation, which may lead to paralytic ileus

Indications and Usage

- EMBEDA™ is an extended-release oral formulation of morphine sulfate and naltrexone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time
- EMBEDA™ is NOT intended for use as a prn analgesic
- EMBEDA™ is not indicated for acute/postoperative pain or if the pain is mild or not expected to persist for an extended period of time. EMBEDA™ is only indicated for postoperative use if the patient is already receiving chronic opioid therapy prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time

For more information, please visit www.EMBEDA.com.
Click here for accompanying full Prescribing Information, including boxed warning.

EMBEDA is a trademark of Alpharma Pharmaceuticals LLC, a wholly owned subsidiary of King Pharmaceuticals®, Inc.

King Pharmaceuticals www.KingPharm.com

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NEW EMBEDA™
(morphine sulfate and naltrexone hydrochloride) Extended Release Capsules

King Pharmaceuticals

King Pharmaceuticals®, Inc.
501 Fifth Street
Bristol, Tennessee 37620

Joe Caso
Sr. Vice President
Trade, GPO/LTC Contracting

EMBEDA™
(morphine sulfate and naltrexone hydrochloride)
Extended Release Capsules

Initial Retail Stocking Offer

September 2009

Dear Retail Pharmacy Customer,

King Pharmaceuticals®, Inc., is pleased to announce the FDA approval and launch of EMBEDA™. Effective immediately, your wholesaler will begin accepting orders for EMBEDA™; shipments to you will begin on or after the week of September 14th.

NDC #	DESCRIPTION	EACH	EACH PER CASE	WAC (Each)
60793-430-01	EMBEDA™ 20 mg/0.8 mg, 100s	1	12	\$393.08
60793-431-01	EMBEDA™ 30 mg/1.2 mg, 100s	1	12	\$427.52
60793-433-01	EMBEDA™ 50 mg/2 mg, 100s	1	12	\$714.45
60793-434-01	EMBEDA™ 60 mg/2.4 mg, 100s	1	12	\$855.04
60793-435-01	EMBEDA™ 80 mg/3.2 mg, 100s	1	12	\$1,139.10
60793-437-01	EMBEDA™ 100 mg/4 mg, 100s	1	6	\$1,428.89

We are also pleased to announce that King has offered wholesalers special incentives for your initial orders for EMBEDA™. These special incentives include:

Off-Invoice Discount
5% discount available on your first order

Distribution Allowance
\$27.00 Discount per unit—EMBEDA™ 20 mg/0.8 mg (subject to limited quantities)
\$29.00 Discount per unit—EMBEDA™ 30 mg/1.2 mg (subject to limited quantities)

Additional Dating Terms
Additional 90 days dating will be provided to wholesalers. Please contact your wholesaler to learn how these special terms apply to you. King will begin aggressive promotion of EMBEDA™ very soon, so you will want to have inventory on your shelves when the first prescription is presented.

Thank you in advance for your support of EMBEDA™.

Click here for accompanying full Prescribing Information, including boxed warning.

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