NEW EMBEDA™

CONTACT YOUR WHOLESALER TO ORDER

HOW SUPPLIED

EMBEDA™						
DOSING STRENGTHS	 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
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 nonprescription 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, and in patients with significant respiratory depression, acute or severe bronchial asthma, and 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™ should be administered cautiously and in reduced dosages in patients with severe renal or hepatic insufficiency, Addison disease, myxedema, hypothyroidism, prostatic hypertrophy or urethral stricture, and in elderly or debilitated patients
- 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
- Consuming EMBEDA™ that has been tampered with by crushing, dissolving, or chewing the extended-release formulation can release sufficient naltrexone to precipitate withdrawal in opioid-dependent individuals. Symptoms of withdrawal usually appear within 5 minutes of ingestion of naltrexone and can last 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 nonopioid medications should be 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
- Common adverse events reported during initiation of therapy include drowsiness, dizziness, constipation, and nausea
- Additional common adverse events reported during clinical studies include constipation, nausea, and somnolence
- Serious adverse events associated with morphine in clinical use include respiratory depression, respiratory arrest, apnea, circulatory depression, cardiac arrest, hypotension, and/or shock

Indications

- 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 indicated for acute/postoperative pain or if the pain is mild or not expected to 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.

King Pharmaceuticals www.KingPharm.com

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

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™.

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