

Medication Guide

EMBEDA® (im-bed-a)

(morphine sulfate and naltrexone hydrochloride) extended-release capsules, CII

EMBEDA is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require daily around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them.
- A long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.
- Not for use to treat pain that is not around-the-clock.

Important information about EMBEDA:

- **Get emergency help right away if you take too much EMBEDA (overdose).** When you first start taking EMBEDA, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur.
- Taking EMBEDA with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your EMBEDA. They could die from taking it. Selling or giving away EMBEDA is against the law.
- Store EMBEDA securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

Do not take EMBEDA if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before taking EMBEDA, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of EMBEDA during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** Not recommended during treatment with EMBEDA. It may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking EMBEDA with certain other medicines can cause serious side effects and could lead to death.

When taking EMBEDA:

- Do not change your dose. Take EMBEDA exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose every 12 or 24 hours, at the same time every day, as instructed by your healthcare provider. Do not take more than your prescribed daily dose within a 24-hour period. If you miss a dose, take your next dose at your usual time.
- Swallow EMBEDA whole. Do not cut, break, chew, crush, dissolve, snort, or inject EMBEDA because this may cause you to overdose and die.
- You should not receive EMBEDA through a nasogastric tube or gastric tube (stomach tube).
- If you cannot swallow EMBEDA capsules, see the detailed Instructions for Use.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking EMBEDA without talking to your healthcare provider.**
- Dispose of expired, unwanted, or unused EMBEDA by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

While taking EMBEDA DO NOT:

- Drive or operate heavy machinery until you know how EMBEDA affects you. EMBEDA can make you sleepy, dizzy, or lightheaded.
- Drink alcohol, or use prescription or over-the-counter medicines containing alcohol. Using products containing alcohol during treatment with EMBEDA may cause you to overdose and die.

The possible side effects of EMBEDA are:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all the possible side effects of EMBEDA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to**

dailymed.nlm.nih.gov

Manufactured for: Pfizer Inc, New York, NY 10017 by: Actavis Elizabeth LLC, 200 Elmora Avenue, Elizabeth, NJ 07207, www.embeda.com or call 1-800-438-1985

This Medication Guide has been approved by the U.S. Food and Drug Administration

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Instructions For Use
EMBEDA[®] (im-bed-a)
(morphine sulfate and naltrexone hydrochloride) extended-release Capsules, CII

- If you cannot swallow EMBEDA[®] capsules, tell your healthcare provider. There may be another way to take EMBEDA[®] that may be right for you. If your healthcare provider tells you that you can take EMBEDA[®] using this other way, follow these steps:

EMBEDA[®] can be opened and the pellets inside the capsule can be sprinkled over applesauce, as follows:

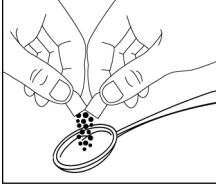


Figure 1

- Open the EMBEDA[®] capsule and sprinkle the pellets over approximately one tablespoon of applesauce (See Figure 1).

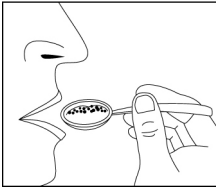


Figure 2

- Swallow all of the applesauce and pellets right away. Do not save any of the applesauce and pellets for another dose (See Figure 2).

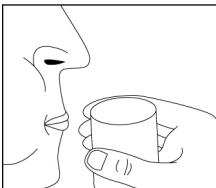


Figure 3

- Rinse your mouth to make sure you have swallowed all of the pellets. Do not chew the pellets (See Figure 3).



Figure 4

- Flush the empty capsule down the toilet right away (See Figure 4).

- You should not receive EMBEDA[®] through a nasogastric tube or gastric tube (stomach tube).

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