

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 treat moderate to severe around-the-clock pain.

Important information about EMBEDA:

- Get emergency help right away if you take too much EMBEDA (overdose). EMBEDA overdose can cause life threatening breathing problems that can lead to death.
- Never give anyone else your EMBEDA. They could die from taking it. Store EMBEDA away from children and in a safe place to prevent stealing or abuse. Selling or giving away EMBEDA is against the law.

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.** EMBEDA may harm your unborn baby.
- **breastfeeding.** EMBEDA passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

When taking EMBEDA:

- Do not change your dose. Take EMBEDA exactly as prescribed by your healthcare provider.
- Take your prescribed dose at the same time every day. Do not take more than your prescribed dose in 24 hours. If you miss a dose, take EMBEDA as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at the same time unless your healthcare provider tells you to.
- Swallow EMBEDA whole. Do not cut, break, chew, crush, dissolve, or inject EMBEDA. 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.**
- After you stop taking EMBEDA, flush any unused capsules down the toilet.

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 that contain alcohol.

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, or you are feeling faint.

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: King Pharmaceuticals, Inc., 501 Fifth Street, Bristol, TN 37620 by: Actavis Elizabeth LLC, 200 Elmora Avenue, Elizabeth, NJ 07207, www.embeda.com or call 1-800-438-1985

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