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2. Embeda

# **Embeda**

Generic name: morphine and naltrexone [ MOR-feen-and-nal-TREX-one ]

Drug class: Narcotic analgesic combinations

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Uses Warnings Before taking Dosage Side effects Interactions

## What is Embeda?

Embeda contains a combination of morphine and naltrexone. Morphine is an opioid pain medication. An opioid is sometimes called a narcotic. Naltrexone blocks certain effects of opioid medication, including feelings of well-being that can lead to opioid abuse.

Embeda is used to treat moderate to severe pain when around-the-clock pain relief is needed for a long time period. Nattrexone is included in this medication to prevent the misuse of the narcotic ingredient.

Embeda is an extended-release opioid pain medicine that is not for use on an as-needed basis for pain.

# **Warnings**

Morphine can slow or stop your breathing, and may be habit-forming. **MISUSE OF EMBEDA CAN CAUSE ADDICTION, OVERDOSE, OR DEATH.** Keep the medication in a place where others cannot get to it.

Do not use Embeda if you have used a MAO inhibitor in the past 14 days, such as isocarboxazid, linezolid, methylene blue injection, phenelzine, rasagiline, selegiline, or translcypromine.

Taking Embeda during pregnancy may cause life-threatening withdrawal symptoms in the newborn.

Fatal side effects can occur if you use this medicine with alcohol, or with other drugs that cause drowsiness or slow your breathing.

# Before taking this medicine

Do not use Embeda if you have used a MAO inhibitor in the past 14 days. A dangerous drug interaction could occur. MAO inhibitors include isocarboxazid, linezolid, methylene blue injection, phenelzine, rasagiline, selegiline, tranylcypromine, and others.

You should not use Embeda if you have ever had an allergic reaction to a narcotic medicine, or if you have:

• severe asthma or breathing problems; or

• a bowel obstruction called paralytic ileus.

To make sure Embeda is safe for you, tell your doctor if you have ever had:

- breathing problems, sleep apnea;
- a head injury, brain tumor, or seizures;
- drug or alcohol addiction, or mental illness;
- enlarged prostate, urination problems;
- · liver or kidney disease;
- · problems with your gallbladder, pancreas, thyroid, or adrenal gland; or
- abnormal curvature of the spine that affects your breathing.

Be sure your doctor knows if you also take stimulant medicine, opioid medicine, herbal products, or medicine for depression, mental illness, Parkinson's disease, migraine headaches, serious infections, or prevention of nausea and vomiting. These medicines may interact with morphine and naltrexone and cause a serious condition called serotonin syndrome.

If you use morphine while you are pregnant, your baby could become dependent on the drug. This can cause life-threatening withdrawal symptoms in the baby after it is born. Babies born dependent on habit-forming medicine may need medical treatment for several weeks.

**Do not breastfeed while taking Embeda.** Morphine and naltrexone can pass into breast milk and cause drowsiness, breathing problems, or death in a nursing baby.

**1** Embeda pregnancy and breastfeeding warnings (more detail)

### How should I use Embeda?

Take Embeda exactly as prescribed. Follow the directions on your prescription label and read all medication guides. **Never use Embeda in larger amounts, or for longer than prescribed.** Tell your doctor if the medicine seems to stop working as well in relieving your pain. Tell your doctor if you feel an increased urge to use more of this medicine.

Stop taking all other around-the-clock narcotic pain medications when you start taking Embeda.

Morphine may be habit-forming, even at regular doses. Never share this medicine with another person, especially someone with a history of drug abuse or addiction. **MISUSE OF NARCOTIC MEDICINE CAN CAUSE ADDICTION**, **OVERDOSE**, **OR DEATH**, **especially in a child or other person using the medicine without a prescription**. Selling or giving away Embeda is against the law.

You may take Embeda with or without food.

Do not crush, break, or open an **extended-release Embeda capsule**. Swallow the capsule whole to avoid exposure to a potentially fatal dose. **Never break open an Embeda capsule to inhale the powder or mix it into a liquid to inject the drug into your vein.** This can cause death.

If you cannot swallow an extended-release capsule whole, open the capsule and sprinkle the medicine into a spoonful of applesauce. Mix only one dose and and swallow this mixture right away without chewing. Drink a glass of water to make sure all the medicine has been swallowed. Flush the empty capsule down a toilet.

Do not stop using Embeda suddenly, or you could have unpleasant withdrawal symptoms. Ask your doctor how to safely stop using this medicine.

Store at room temperature away from moisture, heat, and light. Keep track of your medicine. Morphine is a drug of abuse and you should be aware if anyone is using your medicine improperly or without a prescription.

Do not keep leftover opioid medication. **Just one dose can cause death in someone using this medicine accidentally or improperly.** Ask your pharmacist where to locate a drug take-back disposal program. If there is no take-back program, flush the unused medicine down the toilet.

# **Dosing information**

#### **Usual Adult Dose for Chronic Pain:**

The following dosing recommendations can be considered approaches to what is actually a series of clinical decisions over time in the management of the pain of an individual patient.

All doses expressed as MORPHINE/NALTREXONE

Use as the FIRST OPIOID ANALGESIC or those who are not opioid tolerant:

Initial dose: 20 mg/0.8 mg orally every 24 hours

#### CONVERSION FROM OTHER OPIOIDS:

- -Discontinue all other around-the-clock opioids
- -Initiate at 30 mg/1.2 mg orally every 24 hours

#### CONVERSION FROM OTHER ORAL MORPHINE FORMULATIONS:

-Give one-half of the patient's total daily morphine dose orally every 12 hours OR give the total daily morphine dose orally once daily

#### CONVERSION FROM PARENTERAL MORPHINE OR OTHER OPIOIDS:

- -When converting from parenteral morphine: 1 mg of parenteral morphine is equivalent to approximately 2 to 6 mg of oral morphine; typically the dose of oral morphine is 3 times the daily parenteral morphine dose.
- -When converting from other opioids (parenteral or oral): The initial morphine-naltrexone dose should be one-half of the estimated daily morphine requirement; manage inadequate analgesia by supplementing with immediate-release morphine. CONVERSION FROM METHADONE:
- -Methadone has a long half-life and can accumulate in the plasma; the ratio of other opioid agonists to methadone may vary widely. Close monitoring will be of particular importance.

MAINTENANCE DOSE: Individually titrate to a dose that provides adequate analgesia and minimizes adverse reactions; dose adjustments may be made every 1 to 2 days.

BREAKTHROUGH PAIN: If the level of pain increases after dose stabilization, attempt to identify the source before increasing dose

- -Rescue medication with an appropriate immediate-release analgesia may be helpful
- -For patients experiencing inadequate analgesia with once-daily dosing, a twice daily regimen may be considered.

#### Comments:

- -An opioid tolerant patient is one who has been receiving for 1-week or longer at least: oral morphine 60 mg/day, transdermal fentanyl patch 25 mcg per hour, oral oxycodone 30 mg/day, oral hydromorphone 8 mg/day, oral oxymorphone 25 mg/day, or an equianalgesic dose of another opioid.
- -The 100 mg/4 mg capsules are reserved for use in opioid-tolerant patients only.

- -Monitor patients closely for respiratory depression, especially within the first 24 to 72 hours of initiating therapy.
- -The first dose of this drug may be taken with the last dose of any immediate-release opioid due to its extended-release characteristics.

Use: For the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Detailed Embeda dosage information

# What happens if I miss a dose?

Since Embeda is used for pain, you are not likely to miss a dose. Skip any missed dose if it is almost time for your next scheduled dose. Do not use extra medicine to make up the missed dose.

# What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222. **An Embeda overdose can be fatal, especially in a child or other person using the medicine without a prescription.** Overdose symptoms may include slow heart rate, severe drowsiness, muscle weakness, cold and clammy skin, pinpoint pupils, very slow breathing, or coma.

# What should I avoid while using Embeda?

Do not drink alcohol. Dangerous side effects or death can occur when alcohol is combined with Embeda.

This medication may impair your thinking or reactions. Avoid driving or operating machinery until you know how Embeda will affect you. Dizziness or drowsiness can cause falls, accidents, or severe injuries.

## Embeda side effects

Get emergency medical help if you have **signs of an allergic reaction to Embeda**: hives; difficult breathing; chest pain, anxiety, pounding heartbeats, fainting; swelling of your face, lips, tongue, or throat.

Opioid medicine can slow or stop your breathing, and death may occur. A person caring for you should seek emergency medical attention if you have slow breathing with long pauses, blue colored lips, or if you are hard to wake up.

Call your doctor at once if you have:

- weak or shallow breathing, breathing that stops during sleep;
- a light-headed feeling, like you might pass out;
- seizure (convulsions); or
- low cortisol levels nausea, vomiting, loss of appetite, dizziness, worsening tiredness or weakness.

Seek medical attention right away if you have symptoms of serotonin syndrome, such as: agitation, hallucinations, fever, sweating, shivering, fast heart rate, muscle stiffness, twitching, loss of coordination, nausea, vomiting, or diarrhea.

Serious side effects may be more likely in older adults and those who are overweight, malnourished, or debilitated.

Long-term use of opioid medication may affect fertility (ability to have children) in men or women. It is not known whether opioid effects on fertility are permanent.

Common Embeda side effects may include:

- constipation, nausea, vomiting, stomach pain;
- · drowsiness, dizziness; or
- · headache, tired feeling.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

1 Embeda side effects (more detail)

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# What other drugs will affect Embeda?

Opioid medication can interact with many other drugs and cause dangerous side effects or death. Be sure your doctor knows if you also use:

- other narcotic medications opioid pain medicine or prescription cough medicine;
- a sedative like Valium diazepam, alprazolam, lorazepam, Ativan, Klonopin, Restoril, Tranxene, Versed, Xanax, and others;
- drugs that make you sleepy or slow your breathing a sleeping pill, muscle relaxer, tranquilizer, antidepressant, or antipsychotic medicine; or
- drugs that affect serotonin levels in your body a stimulant, or medicine for depression, Parkinson's disease, migraine headaches, serious infections, or prevention of nausea and vomiting.

This list is not complete. Other drugs may interact with morphine and naltrexone, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible interactions are listed in this medication guide.

**1** Embeda drug interactions (more detail)

# Does Embeda interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.



# More about Embeda (morphine / naltrexone)

- Check interactions
- · Compare alternatives
- Reviews (47)
- Drug images
- · Side effects
- Dosage information
- During pregnancy
- FDA approval history
- Drug class: narcotic analgesic combinations

### **Professional resources**

· Embeda prescribing information

# Related treatment guides

- Chronic Pain
- Pain

# **Further information**

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Embeda only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

#### Medical Disclaimer

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#### **DRUG STATUS**

#### **Availability**

O Discontinued

### **Pregnancy & Lactation**

্প Risk data available

### **CSA Schedule\***

2 High potential for abuse

#### **Approval History**

Drug history at FDA

#### **WADA Class**

റ്റ് Anti-Doping Classification

## **User Reviews & Ratings**

5.1 / 10

47 Reviews

### **Images**

Embeda morphine 20 mg / naltrexone 0.8 mg (EMBEDA 20)





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