MORPHABOND™ ER ('môr-'fa-'bänd e-r) (morphine sulfate) extended-release tablets, CII

MORPHABOND ER 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 MORPHABOND ER:

- Get emergency help right away if you take too much MORPHABOND ER (overdose). When you first start taking MORPHABOND ER, 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 MORPHABOND ER 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 your MORPHABOND ER. They could die from taking it. Store MORPHABOND ER away from children and in a safe place to prevent stealing or abuse. Selling or giving away MORPHABOND ER is against the law.

Do not take MORPHABOND ER if you have:

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

Before taking MORPHABOND ER, 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 MORPHABOND ER 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 MORPHABOND ER. It may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking MORPHABOND ER with certain other medicines can cause serious side effects and could lead to death.

When taking MORPHABOND ER:

- Do not change your dose. Take MORPHABOND ER exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose every 8 to 12 hours, as directed by your healthcare provider. Do not take more than your prescribed dose. If you miss a dose, take your next dose at the usual time.
- Swallow MORPHABOND ER whole. Do not cut, break, chew, crush, dissolve, snort, or inject MORPHABOND ER because this may cause you to overdose and die.
- Call your healthcare provider if the dose you are taking does not control your pain.
- Do not stop taking MORPHABOND ER without talking to your healthcare provider.
- After you stop taking MORPHABOND ER, flush any unused tablets down the toilet.

While taking MORPHABOND ER DO NOT:

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

The possible side effects of MORPHABOND ER 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 MORPHABOND ER. 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 Daiichi Sankyo, Inc.