MEDICATION GUIDE MORPHINE (MOR feen) SULFATE EXTENDED-RELEASE TABLETS, CII Rx only

Morphine sulfate extended-release tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage severe and persistent pain that requires an extended treatment period with a daily opioid pain medicine when other 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-theclock.

Important information about morphine sulfate extended-release tablets:

- Get emergency help or call 911 right away if you take too much morphine sulfate extended-release tablets (overdose). When you first start taking morphine sulfate extended-release tablets, 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. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking morphine sulfate extended-release tablets 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 morphine sulfate extended-release tablets. They could die from taking it. Selling or giving away morphine sulfate extended-release tablets is against the law.

• Store morphine sulfate extended-release tablets securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

Do not take morphine sulfate extended-release tablets if you have:

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

Before taking morphine sulfate extendedrelease tablets, 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, opioid overdose, or mental health problems.

Tell your healthcare provider if you are:

- noticing your pain getting worse. If your pain gets worse after you take morphine sulfate extended-release tablets, do not take more of morphine sulfate extended-release tablets without first talking to your healthcare provider. Talk to your healthcare provider if the pain that you have increases, if you feel more sensitive to pain, or if you have new pain after taking morphine sulfate extended-release tablets.
- pregnant or planning to become pregnant.
 Prolonged use of morphine sulfate extended-release tablets 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 morphine sulfate. It may harm your baby living in a household where there are small children or someone who has abused street or prescription drugs.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

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Taking morphine sulfate extended-release tablets with certain other medicines can cause serious side effects.

When taking morphine sulfate extended-release tablets:

- Do not change your dose. Take morphine sulfate extended-release tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest duration.
- 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 morphine sulfate extended-release tablets whole. Do not cut, break, chew, crush, dissolve, snort, or inject morphine sulfate extended-release tablets 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 morphine sulfate extendedrelease tablets without talking to your healthcare provider.

Dispose of expired, unwanted, or unused morphine sulfate extended-release tablets by taking your drug to an authorized DEA-registered collector or drug take-back program. If one is not available, you can dispose of morphine sulfate extended-release tablets by mixing the product with dirt, cat litter, or coffee grounds; placing the mixture in a sealed plastic bag, and throwing the bag in your trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

While taking morphine sulfate extended-release tablets DO NOT:

- Drive or operate heavy machinery, until you know how morphine sulfate extended-release tablets affect you. Morphine sulfate extendedrelease tablets can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-thecounter medicines that contain alcohol. Using

products containing alcohol during treatment with morphine sulfate extended-release tablets may cause you to overdose and die.

The possible side effects of morphine sulfate extended-release tablets 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 or call 911 right away if you have:

 trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, lightheadedness 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 morphine sulfate extended-release tablets. Call your healthcare provider 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

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

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www.sunpharma.com or call 1-800-818-4555

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