Medication Guide Morphine Sulfate Extended-Release Tablets, CII (MOR feen SUL fate)

Morphine sulfate extended-release tablets are:

- 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 morphine sulfate extended-release tablets:

- Get emergency help right away if you take too many 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.
- 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 extended-release 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, or mental health problems.

Tell your healthcare provider if you are:

- 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 extended-release tablets. It may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. 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 extended-release tablets without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused morphine sulfate extended-release tablets 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 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 extended-release tablets 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 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 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 morphine sulfate extended-release tablets. 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 by: SpecGx LLC, Webster Groves, MO 63119 USA, www.mallinckrodt.com or call 1-800-778-7898

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

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