

MEDICATION GUIDE

Morphine Sulfate (mor-phen) (CII) Oral Solution

IMPORTANT: Keep Morphine Sulfate Oral Solution in a safe place away from children. Accidental use by a child is a medical emergency and can cause death. If a child accidentally takes Morphine Sulfate Oral Solution, get emergency help right away.

Read the Medication Guide that comes with Morphine Sulfate Oral Solution before you start taking it and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about Morphine Sulfate Oral Solution?

Morphine Sulfate Oral Solution can cause serious side effects, including death.

- **Take Morphine Sulfate Oral Solution exactly as prescribed by your healthcare provider. If you take the wrong dose or strength of Morphine Sulfate Oral Solution, you could overdose and die.**
- **It is especially important when you take Morphine Sulfate Oral Solution that you know exactly what dose and strength to take, and the right way to measure your medicine. Your healthcare provider or pharmacist should show you the right way to measure your medicine.**
- **Always use the oral syringe provided with Morphine Sulfate Oral Solution, 100 mg per 5 mL (20 mg/mL) to help make sure you measure the right amount.**
- **The oral solution comes in several different doses (amount of medicine per mL) and strengths (number of mgs).**
- **Do not take the strongest dose of Morphine Sulfate Oral Solution, 100 mg per 5 mL (20 mg/mL) unless you are “opioid tolerant”. Opioid tolerant means that you have been regularly using Morphine Sulfate Oral Solution or another opioid medicine for your constant (around the clock) pain and your body is used to it.**

What is Morphine Sulfate Oral Solution?

Morphine Sulfate Oral Solution is in a group of drugs called narcotic pain relievers. Morphine Sulfate Oral Solution is only for adults who have moderate to severe pain.

- Morphine Sulfate Oral Solution is a prescription medicine that is used to manage moderate to severe pain that is expected to last a short period of time (acute), and pain that continues around-the-clock and is expected to last for a long period of time (chronic).
- Morphine Sulfate Oral Solution is a federally controlled substance (CII) because it is a strong opioid pain medicine that can be abused by people who abuse prescription medicines or street drugs.
- Prevent theft, misuse or abuse. Keep Morphine Sulfate Oral Solution in a safe place to keep it from being stolen. Morphine Sulfate Oral Solution can be a target for people who misuse or abuse prescription medicines or street drugs.

- Never give Morphine Sulfate Oral Solution to anyone else, even if they have the same symptoms you have. It may harm them or even cause death.
- Selling or giving away this medicine is against the law.
- It is not known if Morphine Sulfate Oral Solution is safe and effective in children under age 18 years of age.
- Morphine Sulfate Oral Solution 100 mg per 5 mL (20 mg/mL) is only for adults with moderate to severe pain who are already using an opioid narcotic pain medicine and have been using this medicine continuously for several weeks or longer.

Who should not take Morphine Sulfate Oral Solution?

- Do not take Morphine Sulfate Oral Solution if you:
 - **are allergic to morphine, morphine salts or any of the ingredients in Morphine Sulfate Oral Solution.** See the end of this Medication Guide for a complete list of ingredients in Morphine Sulfate Oral Solution.
 - are having an asthma attack or have severe asthma, trouble breathing, or lung problems
 - have a bowel blockage called paralytic ileus

What should I tell my healthcare provider before taking Morphine Sulfate Oral Solution?

Before taking Morphine Sulfate Oral Solution, tell your healthcare provider if you:

- have trouble breathing or lung problems
- have had a head injury
- have liver or kidney problems
- have had adrenal gland problems, such as Addison's disease
- have severe scoliosis that affects your breathing
- have thyroid problems
- have problems urinating or enlargement of your prostate
- have had convulsions or seizures
- have a past or present drinking problem or alcoholism
- have severe mental problems or hallucinations (seeing or hearing things that are not really there)
- have constipation or other bowel problems
- have problems with your pancreas or gallbladder
- have past or present substance abuse or drug addiction
- plan to have surgery
- have any other medical conditions

- are pregnant or plan to become pregnant. It is not known if Morphine Sulfate Oral Solution will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.

If you take Morphine Sulfate Oral Solution regularly before your baby is born, your newborn baby may have withdrawal symptoms because their body has become used to the medicine. Symptoms of withdrawal in a newborn baby may include:

- irritability
- being very active
- problems sleeping
- high pitched cry
- shaking (tremors)
- vomiting
- diarrhea or more stools than normal
- weight loss
- fever

If you take Morphine Sulfate Oral Solution right before your baby is born, your baby could have breathing problems.

- are breast-feeding or plan to breast-feed. Some Morphine Sulfate passes into your breast milk. A nursing baby could become very sleepy and have problems breathing or feeding well. If you stop breast-feeding, your baby may have withdrawal symptoms. See the list of withdrawal symptoms above. You and your healthcare provider should decide if you will take Morphine Sulfate Oral Solution or breast-feed.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Sometimes the doses of medicines that you take with Morphine Sulfate Oral Solution may need to be changed if used together. Be especially careful about taking other medicines that make you sleepy such as:

- sleeping pills
- other pain medicines
- anti-nausea medicines
- tranquilizers
- antihistamines
- anti-anxiety medicines
- anti-depressants
- anticholinergic medicines
- antibiotic or antifungal medicines
- heart medicines
- anti-seizure medicines
- muscle relaxants
- Tell your healthcare provider if you take cimetidine (Tagamet).
- Do not take Morphine Sulfate Oral Solution if you already take a monoamine oxidase inhibitor medicine (MAOI) or within 14 days after you stop taking an MAOI medicine.
- Do not take any new medicine while using Morphine Sulfate Oral Solution until you have talked with your healthcare provider or pharmacist. They will tell you if it is safe to take other medicines with Morphine Sulfate Oral Solution.

Ask your healthcare provider if you are not sure if your medicine is one listed above.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take Morphine Sulfate Oral Solution?

- **See “What is the most important information I should know about Morphine Sulfate Oral Solution?”**
- **Take Morphine Sulfate Oral Solution exactly as prescribed.** Do not change your dose unless your healthcare provider tells you to. Your healthcare provider may change your dose after seeing how the medicine affects you. Call your healthcare provider if your pain is not well controlled with your prescribed dose of Morphine Sulfate Oral Solution.
- **You can take Morphine Sulfate Oral Solution with or without food.**

- **Make sure you understand exactly how to measure your dose.** Always use the oral syringe provided with your Morphine Sulfate Oral Solution, 100 mg per 5 mL (20 mg/mL) to help make sure you measure the right amount. See the Instructions for Use at the end of this Medication Guide for information about how to measure your dose the right way. Ask your healthcare provider or pharmacist if you are not sure what dose of Morphine Sulfate Oral Solution you should take or if you are not sure how to use the oral syringe.
- **Do not stop taking Morphine Sulfate Oral Solution suddenly.** If you have been taking Morphine Sulfate Oral Solution for more than a few weeks, stopping Morphine Sulfate Oral Solution suddenly can make you sick with withdrawal symptoms (for example, nausea, vomiting, diarrhea, anxiety, and shivering). If your healthcare provider decides you no longer need Morphine Sulfate Oral Solution, ask how to slowly reduce this medicine. Do not stop taking Morphine Sulfate Oral Solution without talking to your healthcare provider.
- **If you miss one dose of Morphine Sulfate Oral Solution** you can take the dose when you remember it if you have pain, or you can wait for the next dose.

Talk with your healthcare provider regularly about your pain to see if you still need to take Morphine Sulfate Oral Solution.

What should I avoid while taking Morphine Sulfate Oral Solution?

- You should not drink alcohol while using Morphine Sulfate Oral Solution. Drinking alcohol with Morphine Sulfate Oral Solution may increase your risk of having dangerous side effects or death.
- **Do not drive, operate heavy machinery, or do other dangerous activities,** especially when you start taking Morphine Sulfate Oral Solution and when your dose is changed, until you know how Morphine Sulfate Oral Solution affects you. Morphine Sulfate Oral Solution can make you sleepy. Ask your healthcare provider to tell you when it is okay to do these activities.

What are the possible side effects of Morphine Sulfate Oral Solution?

- See **“What is the most important information I should know about Morphine Sulfate Oral Solution?”**
- Morphine Sulfate Oral Solution can cause serious breathing problems that can become life-threatening, especially if Morphine Sulfate Oral Solution is used the wrong way. Call your healthcare provider or get help right away if:
 - your breathing slows down
 - you have shallow breathing (little chest movement with breathing)
 - you feel faint, dizzy, confused, or
 - you have any other unusual symptoms

These can be symptoms that you have taken too much Morphine Sulfate Oral Solution (overdose) or the dose is too high for you. **These symptoms may lead to serious problems or death if not treated right away.**

- **Morphine Sulfate Oral Solution can cause your blood pressure to drop.** This can make you feel dizzy if you get up too fast from sitting or lying down. Low blood pressure is also more likely to happen if you take other medicines that can also lower your blood pressure. Severe low blood pressure can happen if you lose blood or take certain other medicines.

- **There is a risk of abuse or addiction with Morphine Sulfate Oral Solution.** The chance is higher if you are or have been addicted to or abused other medicines, street drugs, or alcohol, or if you have a history of mental problems.
- **Morphine Sulfate Oral Solution can cause physical dependence.** Do not stop taking Morphine Sulfate or any other opioid without talking to your healthcare provider about how to slowly stop your medicine. You could become sick with uncomfortable withdrawal symptoms because your body has become used to these medicines. Physical dependence is not the same as drug addiction. Tell your healthcare provider if you have any of these symptoms of withdrawal while slowly stopping Morphine Sulfate Oral Solution:
 - feel restless
 - tearing eyes
 - runny nose
 - yawning
 - sweating
 - chills or hair on your arms “stand up”
 - muscle aches, backache
 - dilated pupils of your eyes
 - feel irritable or anxious
 - trouble sleeping
 - increase in your blood pressure
 - faster breathing, or faster heart beats
 - nausea, loss of appetite, vomiting, diarrhea, stomach-area (abdominal) cramps
- **Common side effects of Morphine Sulfate Oral Solution include:**
 - constipation
 - nausea
 - sleepiness
 - lightheadedness
 - dizziness
 - drowsiness
 - vomiting
 - sweating

Constipation (not often enough or hard bowel movements) is a very common side effect of pain medicines (opioids). Talk to your healthcare provider about dietary changes, and the use of laxatives (medicines to treat constipation) and stool softeners to prevent or treat constipation while taking Morphine Sulfate Oral Solution.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Morphine Sulfate Oral Solution. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Morphine Sulfate Oral Solution?

- Store Morphine Sulfate Oral Solution at room temperature, between 59° F to 86° F (15° C to 30° C).
- After you stop taking Morphine Sulfate Oral Solution, flush the unused oral solution down the toilet.
- **Keep Morphine Sulfate Oral Solution out of the reach of children. Accidental overdose by a child is a medical emergency and can lead to death.**

General information about Morphine Sulfate Oral Solution

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Morphine Sulfate Oral Solution for a condition for which it was not prescribed. **Do not give your Morphine Sulfate Oral Solution to other people, even if they have the same symptoms you have. Selling or giving away Morphine Sulfate Oral Solution may harm others, may cause death, and is against the law.**

This Medication Guide summarizes the most important information about Morphine Sulfate Oral Solution. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Morphine Sulfate Oral Solution that is written for healthcare professionals.

For more information about Morphine Sulfate Oral Solution, go to www.roxane.com or call Roxane Laboratories, Inc. at 1-800-962-8364.

What are the ingredients in Morphine Sulfate Oral Solution?

Active ingredient: morphine sulfate

Inactive ingredients: citric acid, edetate disodium, glycerin, sodium benzoate, sorbitol, and water.

The 10 mg/5 mL oral solution also contains: FD&C Green No. 3 (fast green)

The 20 mg/5 mL oral solution also contains: FD&C Green No. 3 (fast green), methylparaben, and propylparaben

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

Roxane Laboratories, Inc.

Columbus, Ohio 43216

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Instructions for Use

Morphine Sulfate Oral Solution 100 mg per 5 mL (20 mg/mL)

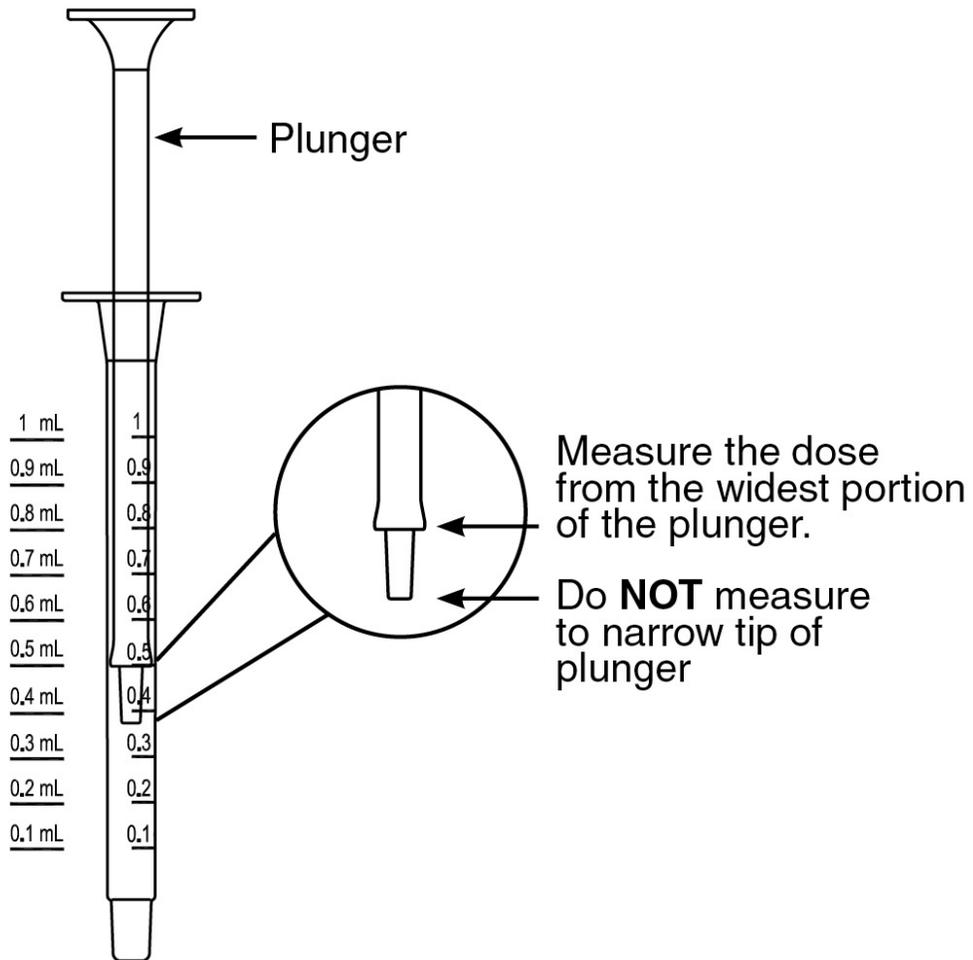
Oral Syringe

Important information about measuring Morphine Sulfate Oral Solution

- **Always use the oral syringe provided with your Morphine Sulfate Oral Solution to make sure you measure the right amount.**
- **Measure the dose of medicine from the widest part of the plunger. Do not measure from the narrow tip. See Figure 1.**

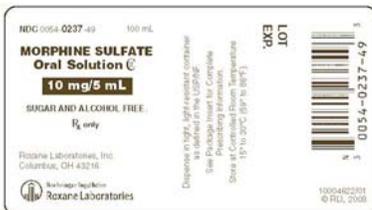
1. Insert the tip of the oral syringe into the medicine bottle.
2. Pull back the plunger to the line that matches the dose prescribed by your healthcare provider.
3. Remove the oral syringe from the medicine bottle.
4. Take your medicine by slowly pushing the plunger until the oral syringe is empty.

Figure 1



10 MG/5 ML ORAL SOLUTION

NDC 0054-0237-49: Bottle of 100 mL



20 MG/5 ML ORAL SOLUTION

NDC 0054-0238-49: Bottle of 100 mL