WARNING: RISK OF MEDICATION ERRORS

See the full prescribing information for important warnings, precautions, and contraindications related to potential risks of accumulation, overdose, and misuse.morphine sulfate oral solution is available in 10 mg per 5 mL, 20 mg per 5 mL, and 100 mg per 5 mL (20 mg/mL) concentrations. The 100 mg per 5 mL (20 mg/mL) concentration is indicated for use in opioid-tolerant patients only. Take care to avoid dosage errors due to confusion between different concentrations and the required dose. Keep Morphine Sulfate Oral Solution out of children's reach. Can cause fatal respiratory depression in children exposed to morphine. Carefully measure the dose to avoid accidental overdose and death. Use caution to ensure the dose is appropriate and administered safely.

DRUG INTERACTIONS

5.6 Hypotensive Effects

Dosage adjustments may be required for patients with renal impairment (creatinine clearance ≤ 30 mL/min), hepatic impairment, or who are concurrently using other medications that may have a potential to increase blood pressure or decrease blood pressure. Use caution when selecting an appropriate starting dosage and titrating up the dose. Consider the following general points regarding opioid conversions.

10.1 Symptoms

Morphine sulfate is contraindicated in patients with respiratory depression in the absence of resuscitative equipment. Morphine sulfate is contraindicated in patients with acute or severe biliary tract or pancreatic disease. Morphine sulfate is contraindicated in patients who have a history of hypersensitivity to opioids.

11 CLINICAL PHARMACOLOGY

Non-opioid analgesics, including non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol, and acetaminophen, and some tricyclic antidepressants (TCAs) may reduce the effectiveness of opioid therapy. Amphetamines, benzodiazepines, barbiturates, and non-benzodiazepine hypnotics may increase the risk of oversedation when used concomitantly with opioids. Dependence, addiction, and abuse have been associated with opioids. See section 11.4 for a list of opioid-approved concomitant medications.

2.2 Initiation of Therapy in Opioid-Naïve Patients

Morphine sulfate is indicated for the relief of moderate to severe acute and chronic pain in opioid-tolerant patients. Consider the following general points regarding opioid conversions.

8 USE IN SPECIFIC Populations

8.1 Pregnancy

CNS depressants: Increased risk of respiratory depression, hypotension, profound sedation, and the tolerability of the morphine by the patient.

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Morphine Sulfate Oral Solution: 10 to 20 mg every 4 hours as needed. (2.2) See section 11.4 for a list of opioid-approved concomitant medications.

8.1 Pregnancy

Morphine sulfate is indicated for the relief of moderate to severe acute and chronic pain when an opioid is appropriate. (1) Morphine sulfate is available in 10 mg per 5 mL (20 mg/mL) miconil solution for the relief of moderate to severe acute and chronic pain in opioid-tolerant patients. (1.1) Keep Morphine Sulfate Oral Solution out of the reach of children.

9 DRUG ABUSE AND DEPENDENCE

5.8 Use in Pancreatic/Biliary Tract Disease

The following dosing recommendations, therefore, can only be considered suggested approaches to conversion.

5.6 Hypotensive Effects

To report SUSPECTED ADVERSE REACTIONS, contact Roxane Laboratories, Inc. at (614) 276-4000 or Technical Product Information at (800) 962-9364 or FDA at 1-800-FDA-1088. Most common adverse reactions seen on initiation of therapy are: constipation, nausea, somnolence, light-headedness, diziness, sedation, vomiting, (4) 5.5 Therapeutic Use in Special Populations

The following are formulations of morphine, an opiate analgesic. (3) Morphine sulfate, given in appropriate analgesic doses, has been used to provide relief of moderate to severe acute and chronic pain in opioid-tolerant patients. (1.1)

5.10 Driving and Operating Machinery

Driving, using machines, or engaging in hazardous activities should be avoided when using opioids because they may impair judgment, reactions, and the ability to perform physically demanding tasks. (5.10)

6 ADVERSE REACTIONS

The following are formulations of morphine, an opiate analgesic. (3) Morphine sulfate, given in appropriate analgesic doses, has been used to provide relief of moderate to severe acute and chronic pain in opioid-tolerant patients. (1.1)

7 DRUG INTERACTIONS

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4 CONTRAINDICATIONS

Morphine Sulfate Oral Solution is available in 10 mg per 5 mL, 20 mg per 5 mL, and 100 mg per 5 mL (20 mg/mL) concentrations. Use caution when prescribing, dispensing, and administering morphine sulfate in situations where the physician or other health care practitioner may be less aware of the patient's cumulative dose. This is due to the inter-patient variability in the potency of opioid drugs and opioid formulations. Therefore, a patient with known opioid dependence may require a lower initial dose than expected. Consider the following general points regarding opioid conversions.

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8.3 Nursing Mothers

8.4 Pediatric Use

8.5 Geriatric Use

8.6 Pregnancy

8.7 Gender

8.8 Nursing Mothers

8.9 Compatibility

9. DRUG ABUSE AND DEPENDENCE

9.1 Abuse

9.2 Dependence

9.3 Withdrawal Syndrome

9.4 Other

9.5 Drug Interactions

9.6 Contraindications

9.7 Overdosage

9.8 Laboratory Tests

9.9 Precautions

9.10 Use In Specific Populations

10. ADVERSE REACTIONS

11. DESCRIPTION

12. MECHANISM OF ACTION

13. CLINICAL PHARMACOLOGY

14. CLINICAL PHARMACOLOGY

15. CLINICAL PHARMACOLOGY

16. CLINICAL PHARMACOLOGY

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