MORPHINE SULFATE INJECTION, USP

OFFICIAL U.S. NATIONAL FORMULARY AND U.S. PHARMACopeIA 37/NF32
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Morphine Sulfate Injection contains morphine, a Schedule II controlled substance. As an opioid, Morphine Sulfate Injection may cause physical and psychological dependence, which can develop rapidly, following repeated use, particularly in patients with a personal or family history of substance abuse (including drug or alcohol abuse/dependence). The risk of dependence can be reduced by using the lowest effective dose for the shortest duration possible. Patients should be instructed to take Morphine Sulfate Injection only as directed, and they should not increase the dose or duration of treatment on their own.

WARNING: Addictive Potential

Addiction and physical dependence may occur within a few days of initiating therapy with Morphine Sulfate Injection and can develop after prolonged use, even if the total daily dose is low. The potential for addiction may increase with the duration of use and the rate of dosage increase. Morphine Sulfate Injection may be abused for nontherapeutic purposes. Physical dependence can result in withdrawal symptoms if the drug is discontinued abruptly or rapidly.

Morphine Sulfate Injection Injection should not be used for the management of patients who require more than 24 hours of continuous or intermittent pain relief. The high potency of Morphine Sulfate Injection makes it suitable only for patients with severe pain requiring analgesics with a rapid onset of action, provided that the patient is being observed carefully to avoid accumulation of the drug. The patient should be maintained on the minimum effective dose, and careful medical evaluation should be performed at regular intervals. Morphine Sulfate Injection injection should not be used in patients who require continuous, long-term administration of a constant or fluctuating opioid dose. Its high potency makes it necessary to have precise control over the dosage and rate of administration.

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Morphine is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be
and monitor for signs of central nervous system and respiratory depression

1. Elderly patients (aged 65 years or older) may have increased sensitivity to morphine. In general, use caution when

2. The pharmacodynamic effects of morphine in the elderly are more variable than in the younger population. Older

3. Infants exposed to Morphine Sulfate Injection through breast milk should be monitored for excess sedation and

4. Fetal and/or postnatal exposure to morphine in mice and rats has been shown to result in morphological changes

5. Prescription drug abuse is the intentional non-therapeutic use of a prescription drug, even once, for its rewarding

6. Morphine Sulfate Injection contains a preservative with a high potential for abuse similar to or greater than those of

7. The brand names mentioned in this document are the trademarks of their respective owners.

8. For more information concerning this drug, please call Fresenius Kabi USA, LLC at 1-800-551-7176.

9. Do not use if package has been damaged.

10. Connect the syringe to appropriate injection connection depending on route of administration.

11. Acceptable methods include intramuscular injection, intravenous injection, and subcutaneous injection. Following

12. External Collar: The expected cleanup of the patient following the administration of a single dose of the drug is

13. The external collar must be removed before administration.

14. Preservative-free: The chemical preservative in this product is propylene glycol. The device is preservative-free.

15. Figure 1: A diagram of the external collar and connector assembly

16. The figure is not to scale.

17. The manufacturer's date code is located on the drug container using a roll of perforated film or a barcode scanner.

18. The drug container is made of clear plastic wrap around the external collar. (See Figure 1)

19. Do not remove the label or dispose of the product in the usual way or if it contains a precipitate.

20. The date of manufacture is embossed on the product container.

21. The drug container is made of clear plastic wrap around the external collar. (See Figure 1)

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