

Data Sheet

MORPHINE SULPHATE INJECTION 1 mg/ml

Presentation

Clear, colourless or almost colourless, sterile solution in syringe for injection.

Uses

Actions:

Morphine sulphate is a phenanthrene-derivative opiate agonist. It is the principal alkaloid of opium. Peak analgesia occurs 20 minutes following IV infusion. Maximal respiratory depression occurs within 3 - 7 minutes. Analgesia may be maintained for up to 7 hours. Although sensitivity of the respiratory centre returns to normal within 2 - 3 hours, respiratory minute volumes may remain below normal for 4 - 5 hours.

Pharmacokinetics

IV morphine sulphate is immediately bioavailable, since no absorption is required. Morphine is metabolised principally in the liver and undergoes conjugation with glucuronic acid at the 3-hydroxyl group. Secondary conjugation may also occur at the 6-hydroxyl group to form 3,6-digluconuride. Morphine is excreted in the urine, mainly as the gluconuride and in smaller amounts as the digluconuride and as unchanged drug. About 90% of the drug is excreted within 24 hours of giving the last dose. About 7 - 10% is excreted in faeces, with a large portion of this excreted via bile.

Indications

Morphine sulphate is a strong analgesic, used for the symptomatic relief of moderate to severe pain, especially that associated with neoplastic disease, myocardial infarction and surgery. In addition to relieving pain, it also alleviates the anxiety associated with severe pain and is useful as a hypnotic where sleeplessness is due to pain.

Morphine reduces intestinal motility and has been used in the symptomatic treatment of diarrhoea. It also relieves the dyspnoea of left ventricular failure and of pulmonary oedema. It may be used to control the intractable cough associated with terminal lung cancer.

Morphine can be used as an adjunct to anaesthesia for pain relief and to allay anxiety, and has been used in high doses as a general anaesthetic for specialised purposes.

Dosage and Administration

Morphine sulphate can be given by slow continuous subcutaneous or intravenous infusion or by a controlled infusion device. The rate of continuous intravenous or subcutaneous infusion must be individualised according to the patient's requirements. The dosage should be varied on the severity of the pain.

Contraindications

Morphine is generally contraindicated in respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion. It should be used with extreme caution in patients with decreased respiratory reserve and should not be given during an attack of bronchial asthma or in heart failure secondary to chronic lung disease. It is also contraindicated in the presence of acute alcoholism, head injuries and conditions in which intracranial pressure is raised.

Warnings and Precautions

In normal doses, the most common side effects are nausea, vomiting, constipation, drowsiness and confusion. Dry mouth, sweating, facial flushing, vertigo, bradycardia, palpitations, orthostatic hypotension, hypothermia, restlessness, changes in mood, hallucinations and miosis may also occur. These effects tend to occur more commonly in ambulant patients than in those at rest in bed and in those without severe pain. Raised intracranial pressure occurs in some patients and muscle rigidity have been reported following high doses.

Miscellaneous side effects include headache, anxiety, depression of cough reflex, interference with thermal regulation and oliguria..

In general side effects may be reversed by narcotic antagonists. The euphoric activity of morphine has lead to abuse and dependence.

Dependence may occur after 1 - 2 weeks treatment at therapeutic doses and has been found after 2 - 3 days. Withdrawal therapy may be required.

Pregnancy and lactation

Safe use in pregnancy has not been established. Opiate agonists should be avoided during labour when delivery of a premature neonate is anticipated. Morphine is readily distributed into the foetal circulation, so resuscitative equipment for the infant should be readily available.

Morphine is distributed in the breast milk, although usual doses do not produce clinically important concentrations. The risk of high levels should be considered when patients are receiving high morphine doses or in patients with a history of abuse.

Effect on ability to drive or use machines

It would be dangerous to drive or operate machinery following a morphine infusion.

Adverse effects

Evidence of histamine release, such as urticaria and pruritus, wheals and/or local tissue irritation may occur. Contact dermatitis has been reported and pain and irritation may occur on injection. Anaphylactic reactions following intravenous injections have been reported rarely

Interactions

The administration of morphine and other narcotic analgesics is contraindicated in patients taking monoamine oxidase inhibitors or within 10 days of stopping such treatment. The depressant effects of morphine are enhanced by depressants of the central nervous system such as anaesthetics, hypnotics, sedatives and phenothiazines.

Overdosage

Large doses produce respiratory depression and hypotension, with circulatory failure and deepening coma. Convulsions may occur, especially in infants and children. Rhabdomyolysis progressing to renal failure has been reported in overdosage. Death may occur from respiratory failure. Toxic doses vary considerably with the individual and regular users may tolerate large doses.

The triad of coma, pinpoint pupils and respiratory depression (with or without concomitant CNS depression) is considered indicative of overdosage. Dilation of the pupils occurs as hypoxia develops. Pulmonary oedema after overdosage is a common cause of fatalities among addicts.

In acute poisoning by an opioid taken by mouth, the stomach should be emptied. A laxative may be given to aid peristalsis. Since respiratory arrest may result either through direct depression of the respiratory centre or as a result of hypoxia, primary attention should be

given to the establishment of adequate respiratory exchange through provision of a patent airway and institution of assisted or controlled ventilation. The narcotic antagonist, naloxone, is a specific antidote. Naloxone (0.4 mg - 2 mg repeated at intervals of 2 - 3 minutes if necessary up to 10 minutes) should be administered intravenously, simultaneously with respiratory resuscitation. As the duration of effect of naloxone is considerably shorter than that of epidural or intrathecal morphine, repeated administration may be necessary. Patients should be closely observed for evidence of re-narcotisation.

Adequate facilities should be available for post operative monitoring and ventilation. Resuscitative equipment, oxygen and a narcotic antagonist should be readily available to manage apnoea.

Pharmaceutical precautions

Solutions should be stored below 25°, protected from light in a controlled drug safe. The solution is designated for single use only and any unused portion should be discarded. The solution should not be used if it is not colourless or almost colourless. Strict attention to aseptic technique is required.

The product should not be mixed with other medication prior to infusion unless compatibility is established.

The syringes should be stored at room temperature and used within 10 months from the date of manufacture.

Medicine classification

Controlled drug B1.

Package quantities

10 ml, 30 ml and 50 ml syringes

Name and address

Biomed Limited
52 Carrington Road
Point Chevalier
AUCKLAND

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