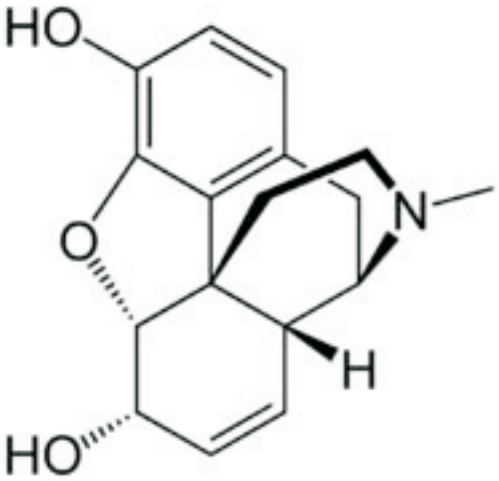
Taj Pharmaceuticals Ltd.

Morphine sulphate

CAS No. : 64-31-3



Systematic (IUPAC)name (5a,6a)-7,8-didehydro-4,5-epoxy-17-methylmorphinan-3,6-diol

Chemical data
Formula C17H19NO3
Mol. mass 285.34
Pharmacokinetic data
Bioavailability ~25% (oral); 100% (IV);
Protein binding 30–40%
Metabolism Hepatic 90%
Half life 2–3 h
Excretion Renal 90%, biliary 10%

DRUG DESCRIPTION

Morphine sulphate Cas No. 64-31-3

Morphine can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing Morphine sulphate in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion. Chemically, morphine sulfate is 7,8-didehydro-4,5a-epoxy-17-methy lmorphinan-3,6a-diol sulfate (2:1) (salt) pentahydrate

Morphine sulphate Tablets are opiate analgesics supplied in 15, 30, 60, 100 and 200 mg tablet strengths. The tablet strengths describe the amount of morphine per tablet as the pentahydrated sulfate salt (morphine sulfate, USP). Morphine sulphate Controlled-release Tablets 15 mg, 30 mg, 60 mg, 100 mg, and 200 mg contain the following inactive ingredients: cetostearyl alcohol, hydroxyethyl cellulose, hypromellose, magnesium stearate, polyethylene glycol, talc and titanium dioxide.

DOSAGE

Morphine Sulphate DOSAGEThe dosage is based on your medical condition and response to treatment. Do not increase your dose, take the medication more frequently, or take it for a longer time than prescribed. Properly stop the medication when so directed. You may also take quick-acting narcotic pain medications for sudden (breakthrough) pain if so directed by your doctor. Also follow your doctor's or pharmacist's instructions for safely using non-narcotic pain relievers (such as naproxen, ibuprofen). If you have been using other long-acting narcotic pain medications or narcotic patches regularly, check with your doctor or pharmacist because you may need to stop using them before you start using this medication. If you are currently using a narcotic patch (such as fentanyl), the effects may continue after it is removed. Ask your doctor or pharmacist when it will be safe to start taking this medication (usually 18 hours after removing the patch).

Take this medication by mouth with or without food, usually 2 or 3 times daily (every 8 or 12 hours) or as directed by your doctor. If you have nausea, it may help to take this drug with food. Consult your doctor or pharmacist about other ways to decrease nausea (such as taking antihistamines, lying down for 1 to 2 hours with as little head movement as possible).

TAJ PHARMACEUTICALS LIMITED

MORPHINE SULPHATE

Formula C17H19NO3
Cas No. **64-31-3**

SIDE EFFECTS

The adverse reactions caused by morphine are essentially those observed with other analgesics. They include the following major hazards: respiratory depression, apnea, and to a lesser degree, circulatory depression, respiratory arrest, shock, and cardiac arrest.
Most Frequently Observed

Constipation, lightheadedness, dizziness, sedation, nausea, vomiting, sweating, dysphoria, and euphoria.

Some of these effects seem to be more prominent in ambulatory patients and in those not experiencing severe pain. Some adverse reactions in ambulatory patients may be alleviated if the patient lies down.

Less Frequently Observed Reactions

Central Nervous System: Weakness, headache, agitation, tremor, uncoordinated muscle movements, seizure, alterations of mood (nervousness, apprehension, depression, floating feelings), dreams, muscle rigidity, transient hallucinations and disorientation, visual disturbances, insomnia, increased intracranial pressure

Gastrointestinal: Dry mouth, biliary tract spasm, laryngospasm, anorexia, diarrhea, cramps, taste alteration, constipation, ileus, intestinal obstruction, dyspepsia, increases in hepatic enzymes

Cardiovascular: Flushing of the face, chills, tachycardia, bradycardia, palpitation, faintness, syncope, hypotension, hypertension

Genitourinary: Urine retention or hesitance, amenorrhea, reduced libido and/or potency

Dermatologic: Pruritus, urticaria, other skin rashes, edema, diaphoresis

Other: Antidiuretic effect, paresthesia, bronchospasm, muscle tremor, blurred vision, nystagmus, diplopia, miosis, anaphylaxis

PRECAUTIONS

Morphine sulphate Tablets are a controlled-release oral formulation of morphine sulfate indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. Morphine sulphate does not release morphine continuously over the course of a dosing interval. The administration of single doses of Morphine sulphate on a q12h dosing schedule will result in higher peak and lower trough plasma levels than those that occur when an identical daily dose of morphine is administered using conventional oral formulations on a q4h regimen. The clinical significance of greater fluctuations in morphine plasma level has not been systematically evaluated.

Selection of patients for treatment with Morphine sulphate® should be governed by the same principles that apply to the use of morphine or other potent opioid analgesics

Specifically, the increased risks associated with its use in the following populations should be considered: the elderly or debilitated and those with severe impairment of hepatic, pulmonary, or renal function; myxedema or hypothyroidism; adrenocortical insufficiency (e.g., Addison's Disease); CNS depression or coma; toxic psychosis; prostatic hypertrophy or urethral stricture; acute alcoholism; delirium tremens; kyphoscoliosis or inability to swallow.

The administration of morphine, like all opioid analgesics, may obscure the diagnosis or clinical course in patients with acute abdominal conditions.

Morphine may aggravate convulsions in patients with convulsive disorders, and all opioids may induce or aggravate seizures in some clinical settings.

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:
http://www.tajapi.com
or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.
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