

PACKAGE LEAFLET: INFORMATION FOR THE USER

Morphine Sulfate 1mg/ml & 2mg/ml Solution for Injection

Morphine Sulfate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
 - If you have any further questions, ask your doctor or pharmacist.
 - If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
- See section 4.

This medicine will be referred to as Morphine Sulfate Solution for Injection in the rest of this leaflet.

What is in this leaflet

1. What Morphine Sulfate Solution for Injection is and what it is used for
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1. What Morphine Sulfate Solution for Injection is and what it is used for

Morphine is an alkaloid with powerful pain relieving properties.

This medicine is a solution for injection that has been prepared in water so that it can be used with specially designed pumps which provide a continuous injection into the body. It is used in the long term relief of moderate to severe pain, such as the pain caused by surgery, heart attacks and cancer. This medicine also helps to reduce the anxiety and sleeplessness which may be caused by the pain.

2. Before you are given Morphine Sulfate Solution for Injection

You should not be given Morphine Sulfate Solution for Injection if:

- you are allergic to Morphine Sulfate or any of the other ingredients listed in section 6
- you suffer from asthma attack, shallow breathing and other breathing difficulties
- you suffer from liver or kidney problems
- you are suffering from severe stomach pains
- you are currently taking drugs used to treat depression known as monoamine oxidase inhibitors (MAOIs) or have taken them in the last 2 weeks
- you are suffering from severe headaches or have suffered a head injury
- you suffer from a convulsive disorder (fits) such as epilepsy
- you are suffering from a problem that could cause paralysis of the small intestine (paralytic ileus)
- you suffer from alcoholism
- you have been told you are suffering from a condition known as delayed gastric emptying, the symptoms of which include heartburn, feeling sick or being sick and feeling full quickly whilst eating
- you suffer from severe heart and lung problems

Warnings and precautions

Talk to your doctor or pharmacist before being given Morphine Sulfate Solution for Injection if:

- you suffer from low blood pressure
- you suffer from problems related to your adrenal gland (the organ responsible for stress levels), including Addison's disease (an illness caused by a lack of the hormone cortisol which controls stress levels)
- you have any lung problems, in particular emphysema (enlarged and damaged lungs)
- you have any prostate problems
- you have had an operation in the last 24 hours
- you are extremely overweight
- you suffer from spine problems
- you think you may be in shock as there is a risk of coma
- you suffer from thyroid problems
- you are currently having an asthma attack or you usually suffer from asthma
- you are pregnant or breast-feeding
- you are elderly or ill. The dose may have to be reduced
- you are dependent on morphine
- you suffer from problems with your pancreas
- you suffer from a muscle disorder known as myasthenia gravis
- you suffer from an irregular heartbeat
- you have been told you suffer from a severe heart problem known as cor pulmonale
- you suffer from bowel problems
- you have liver problems
- you have kidney problems

Talk to your doctor or pharmacist if you experience any of the following symptoms while being given Morphine Sulfate Solution for Injection:

- Increased sensitivity to pain despite the fact that you are taking increasing doses (hyperalgesia). Your doctor will decide whether you will need a change in dose or a change in strong analgesic ("painkiller"), (see section 2).
- Weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of the adrenals producing too little of the hormone cortisol, and you may need to take hormone supplement.
- Loss of libido, impotence, cessation of menstruation. This may be because of decreased sex hormone production.
- If you have once been dependent on drugs or alcohol. Also tell if you feel that you are becoming dependent on X while you are using it. You may have started to think a lot about when you can take the next dose, even if you do not need it for the pain.
- Abstinence symptoms or dependence. The most common abstinence symptoms are mentioned in section 3. If this occurs, your doctor may change the type of medicine or the times between doses.

Other medicines and Morphine Sulfate Solution for Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without prescription.

Please tell your doctor if you are taking any of the following medicines:

- medicines used to treat severe depression known as monoamine oxidase inhibitors (MAOIs) e.g. moclobemide. Tell your doctor even if you have stopped taking them within the last two weeks
 - medicines used to help you to relax (sedatives)
 - medicines used to help you to sleep (hypnotics)
 - medicines used to treat depression (tricyclics)
 - medicines used to treat serious mental disorders (phenothiazines and dexamphetamine)
 - mexiletine, a medicine used to treat an irregular heartbeat
 - medicines used to treat anxiety (anxiolytics) e.g. hydroxyzine
 - cisapride, a medicine used to treat acid reflux and heartburn
 - medicines used to prevent sickness e.g. domperidone and metoclopramide
 - selegiline, a medicine used to treat Parkinson's disease
 - cimetidine and ranitidine, medicines used to treat stomach ulcers
 - anaesthetics
 - certain antibiotics, used to treat infections (e.g. ciprofloxacin and linezolid)
 - medicines used to treat or prevent heart attack e.g. propranolol and esmolol
 - medicines used to relax muscles and ease pain and stiffness caused by acute bone and muscle problems (muscle relaxants)
 - ritonavir, an antiviral medicine used to prevent human immunodeficiency virus (HIV) from multiplying in your body
 - disulfiram, a medicine used to prevent alcohol consumption
 - medicines that increase urine production in the kidneys (diuretics or water pills)
 - rifampicin to treat e.g. tuberculosis
 - Concomitant use of Morphine Sulfate Injection and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.
- However, if your doctor does prescribe Morphine Sulfate Injection together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.
- Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Pregnancy, breast-feeding and fertility:

If you are pregnant, trying for a baby or breast-feeding you should ask your doctor for advice before you are given this medicine. You should not be given morphine if you are pregnant or think you might be pregnant unless you have discussed this with your doctor first. If you are given morphine during pregnancy and become dependent on it, there is a risk that the new-born baby may also be dependent and suffer from withdrawal symptoms following delivery. If you are given morphine during labour there is a risk that you could be sick and have breathing difficulties, or the baby could have difficulty starting breathing. If you are breast-feeding, ask your doctor for advice before taking this medicine.

Driving and using machines

This medicine may cause drowsiness. If you are affected do not drive or use machines.

This medicine can affect your ability to drive and operate machinery as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Having Morphine Sulfate Solution for Injection with alcohol

You are advised not to drink alcohol during your treatment with this medicine.

Morphine Sulfate Solution for Injection contains sodium

This medicine contains 3.54 mg sodium (main component of cooking/table salt) in each dose. This is equivalent to 0.18 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How Morphine Sulfate Solution for Injection will be given

Morphine Sulfate Injection is given to you as a slow infusion (drip) into the vein. It is given as Patient Controlled Analgesia (PCA), meaning that you will be able to administer pain relief to yourself rather than your doctor or nurse doing it for you.

Your doctor will still determine the dose you need however you will be able to give yourself pain relief as and when you need it. You will not be able to give yourself more than the maximum dose.

Under some circumstances your doctor may prescribe a dose higher than those stated here.

Adults

Loading dose

Loading doses of typically between 1mg and 10mg (maximum 15mg) of morphine sulfate may be given by intravenous infusion over

four or five minutes. The loading dose used will depend upon the patient's diagnosis and conditions.

PCA demand dose

An initial demand dose of 1mg Morphine Sulfate Injection with a lockout period of 5 to 10 minutes is recommended. Dosages may vary depending on the loading dose, the tolerance and condition of the patient, and whether a background infusion of morphine sulfate is being given.

The patient should be specifically monitored for pain, sedation and respiratory rate during the first few hours of treatment to ensure that the dosage regimen is suitable.

The duration of treatment should be kept to a minimum, although dependence and tolerance are not generally a problem when morphine is used legitimately in patients with opioid-sensitive pain.

Use in Children

Not recommended for children under 12 years

The elderly and ill

It is recommended that a reduced dose be used

If you are given too much of Morphine Sulfate Injection:

This medicine will be given to you in hospital so it is unlikely you will receive too much. Your doctor has information on how to recognise and treat an overdose.

People who have taken an overdose may get pneumonia from inhaling vomit or foreign matter, symptoms may include breathlessness, cough and fever. People who have taken an overdose may also have breathing difficulties leading to unconsciousness or even death.

If you experience any of the following, tell your doctor immediately:

- difficulty in breathing
- pinpoint pupils
- low blood pressure
- feeling cold
- fits
- confusion
- severe drowsiness
- slow heartbeat
- severe nervousness or restlessness

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

If you stop using Morphine Sulfate Solution for Injection

Do not stop treatment with Morphine Sulfate Solution for Injection unless agreed with your doctor. If you want to stop the treatment with Morphine Sulfate Injection, ask your doctor how to slowly decrease the doses so you avoid abstinence symptoms. Abstinence symptoms may include body aches, tremors, diarrhoea, stomach pain, nausea, flu-like symptoms, fast heartbeat and large pupils. Psychological symptoms include an intense feeling of unsatisfaction, anxiety and irritability.

4. Possible Side Effects

Like all medicines Morphine Sulfate Solution for Injection can cause side effects, although not everybody gets them.

Repeated use of morphine can result in tolerance and addiction

If any of the following symptoms occur tell your doctor or nurse immediately. These are symptoms of a serious allergic reaction.

- sudden wheeziness and tightness of chest
- swelling of eyelids, face or lips
- skin lumps or hives
- skin rash (red spots), itchiness, fever
- collapse
- rise in pressure around the brain
- Serious allergic reaction which causes difficulty in breathing or dizziness.

Other side effects include:

- constipation
- drowsiness
- difficulty thinking clearly
- dry mouth
- slowed breathing
- hallucinations (seeing or hearing things that are not real)
- dizziness
- feeling or being sick
- itching
- difficulty focusing your eyes or blurred vision
- muscle spasms
- feeling your heart beat (palpitations)
- feeling cold (hypothermia)
- feeling restless
- pinpoint pupils
- enlarged pupils
- flushing
- sore, red and swollen skin
- loss of appetite
- indigestion
- worsening of a condition that affects the pancreas known as pancreatitis. The symptoms of this include stomach pain and feeling or being sick.
- changes in the way things taste
- seizures (fits)
- sweating
- feeling faint on standing up
- severe confusion
- mood changes, feeling extremely happy for no particular reason, or a feeling of emotional and mental unease (dysphoria)
- headache
- vertigo
- difficulty or pain in passing urine
- passing less urine than usual
- biliary spasm (causing pain in the right side of your abdomen, particularly after eating a meal, which may spread towards your right shoulder)
- slow and fast heart beat
- pain and irritation at the injection site
- reduced sexual drive or impotence after long term use
- unusual weakness (asthenia)
- infertility
- erectile dysfunction
- no menstrual periods
- temporary paralysis or weakness of muscles
- swelling of hands, ankles or feet (oedema)
- low and high blood pressure
- adrenal glands not working properly
- tingling or numbness of the hands or feet
- sleep disturbance
- an increased sensitivity to pain
- abstinence symptoms or dependence (for symptoms see section 3: If you stop taking Morphine Sulfate Solution for Injection)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to Store Morphine Sulfate Solution for Injection

Keep this medicine out of the sight and reach of children.

You should not be given Morphine Sulfate Injection after the expiry date on the vial and carton label. The expiry date refers to the last day of that month. The doctor or nurse will check that the product has not passed this date.

Store below 25°C. Keep the vials in

the outer carton in order to protect from light. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

6. Contents of the pack and other information**What Morphine Sulfate Injection contains**

The active ingredient: morphine sulfate 0.1 %w/v or 0.2%w/v.
The other ingredients: sodium chloride 0.9% and water for injections.

What Morphine Sulfate Injection looks like and contents of the pack:

Morphine Sulfate Injection is a sterile solution, supplied in clear glass vials. Each vial contains 50ml or 100ml of the solution.

Marketing Authorisation Holder:

Aurum Pharmaceuticals Ltd., Bampton Road, Harold Hill, Romford, RM3 8UG, UK

Manufacturer:

Panpharma GmbH
Busenstrasse 4, D-22946 Trittau
Germany

Product Licence Number(s):

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The following information is intended for healthcare professionals only:

Physicochemical incompatibility (formation of precipitates) has been demonstrated between solutions of morphine sulphate and 5-fluorouracil