

PACKAGE LEAFLET: INFORMATION FOR THE 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.
<ul style="list-style-type: none"> • 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
2. Before you are given Morphine Sulfate Solution for Injection
3. How Morphine Sulfate Solution for Injection will be given
4. Possible side effects
5. How to store Morphine Sulfate Solution for Injection
6. Contents of the pack and other information

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

Tolerance, dependence, and addiction

This medicine contains morphine which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Morphine Sulfate Solution for Injection can also lead to dependence, abuse, and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Morphine Sulfate Solution for Injection if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
 - You are a smoker.
 - You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses
- If you notice any of the following signs whilst taking Morphine Sulfate Solution for Injection, it could be a sign that you have become dependent or addicted:
- You need to take the medicine for longer than advised by your doctor
 - You need to take more than the recommended dose
 - You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
 - You have made repeated, unsuccessful attempts to quit or control the use of the medicine
 - When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ("withdrawal effects")

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3. If you stop taking Morphine Sulfate Solution for Injection).

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 your doctor or pharmacist 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.

Acute generalized exanthematous pustulosis (AGEP) has been reported in association with Morphine Sulfate Solution for Injection treatment. Symptoms usually occur within the first 10 days of treatment. Tell your doctor if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Morphine Sulfate Solution for Injection or other opioids. Stop using Morphine Sulfate Solution for Injection and seek medical attention immediately, if you notice any of the following symptoms: blistering, widespread scaly skin or pus-filled spots together with fever.

Sleep-related breathing disorders
Morphine Sulfate Solution for Injection can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

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.

A large number of drugs can interact with Morphine Sulfate Injection which can significantly alter their effect. These drugs include:

- 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
- Some medicines used to treat blood clots (e.g. clopidogrel, prasugrel, ticagrelor) may have a delayed and decreased effect when taken together with morphine
- Concomitant use of Morphine Sulfate Solution for 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.
- gabapentin or pregabalin to treat epilepsy and pain due to nerve problems (neuropathic pain)

However, if your doctor does prescribe Morphine Sulfate Solution for 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 newborn 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.

Continued overleaf

- 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 Solution for 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.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Morphine Sulfate Solution for Injection, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also, If you stop taking Morphine Sulfate Solution for Injection, in this section).

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 Solution for 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 Solution for 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 Solution for 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

Stop using Morphine Sulfate Solution for Injection and seek medical attention immediately if you notice any of the following symptoms:

- 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.
- severe skin reaction with blistering, widespread scaly skin, pus-filled spots together with fever. This could be a condition called Acute Generalized Exanthematous Pustulosis (AGEP).

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")
- sleep apnoea (breathing pauses during sleep)
- Symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system, e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever.

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 Solution for 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 Solution for 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 Solution for Injection looks like and contents of the pack:

Morphine Sulfate Solution for 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
Bunsenstrasse 4, D-22946 Trittau
Germany

Product Licence Number(s):

PL 12064/0007
PL 12064/0008

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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



DEVELOPMENT ARTWORK

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12064/0007 PL 12064/0008

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Version B:		
Version C:		
Version D:		
Version E:		
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Version H:		
Version I:		
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