

Package Leaflet: Information for the user
Morphine Sulfate 1mg in 1mL 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, nurse or pharmacist.**
- **If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.**



What is in this leaflet:

- 1. What Morphine Sulfate 1mg in 1mL Solution for Injection is and what it is used for**
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1. What Morphine Sulfate 1mg in 1mL Solution for Injection is and what it is used for

Morphine Sulfate, the active ingredient, belongs to a group of strong painkilling medicines called opioids which must be used only under a doctor's instruction. 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. What you need to know before you use Morphine Sulfate 1mg in 1mL Solution for Injection

Do not use Morphine Sulfate 1mg in 1mL Solution for Injection if you:

- Are allergic to Morphine Sulfate or any other strong painkilling drugs
- Have a history of alcohol abuse
- Suffer from malfunctioning of the adrenal gland (phaeochromocytoma)
- Have suffered a head injury
- Are at risk of a paralytic ileus (reduced gut motility)
- Have acute respiratory depression (breathlessness)
- Have raised pressure inside your skull

Check with your doctor if you are concerned about any of the above.

Warnings and Precautions:

Talk to your doctor, pharmacist or nurse before using Morphine Sulfate 1mg in 1mL Solution for Injection if you:

- Are pregnant or breast feeding
- Have taken this medicine in the last two weeks
- Suffer from asthma, chronic bronchitis or have any other illness which causes breathing difficulties
- Suffer from kidney or liver problems
- Suffer from stomach or bowel problems
- Have difficulty in passing urine due to an enlarged prostate
- Suffer from bad headaches or feel sick
- Suffer from epilepsy or other fits
- Suffer from poor blood supply to the heart or other heart problems
- Have low blood pressure (hypotension)
- Have a tumour of the adrenal gland
- Suffer from myasthenia gravis
- Suffer from pain from gallstones (biliary colic)
- Suffer from thyroid problems
- Are elderly and/or debilitated
- 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 Morphine Sulfate 1mg in 1mL Solution for Injection 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.

Check with your doctor if you are concerned about any of the above. This medicine is only suitable for long lasting pain and is not intended for pain which only lasts for short periods. NEVER give your medication to other people even if their symptoms are the same as yours.

Other Medicines and Morphine Sulfate 1mg in 1mL Solution for Injection

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is especially important if you are taking any of the medicines mentioned below or medicines for:

- Rifampicin to treat e.g. tuberculosis
- Concomitant use of Morphine Sulfate 1mg in 1mL 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. However if your doctor does prescribe Morphine Sulfate 1mg in 1mL 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.

- Are taking medicines to treat depression
- Are taking medicines for sickness (phenothiazines), for drying secretions (anticholinergics e.g. hyoscine) or other pain killers
- Have taken one of a group of drugs called monoamine oxidase inhibitors (used to treat depression) within the last two weeks
- Are taking anti-psychotics, cimetidine, domperidone or metoclopramide
- Are taking esmolol, mexiletine or ritonavir

Pregnancy

If Morphine Sulfate 1mg in 1mL Solution for Injection is used for a long time during pregnancy, there is a risk of the new-born child having drug withdrawal (abstinence) symptoms which should be treated by a doctor.

Driving and using machines

You must not use machinery whilst using this medicine.

The medicine can affect your ability to drive 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 instruction 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.

Morphine Sulfate 1mg in 1mL contains Sodium Chloride

This medicine contains 3.6mg sodium (main component of cooking/table salt) in each mL. This is equivalent to 0.2% of the WHO recommended daily intake of 2g sodium for an adult.



Additional information for Healthcare Professionals
(as stated on the Summary of Product Characteristics)

Therapeutic Indications

Morphine Sulfate Solution for Injection is indicated for the relief of moderate to severe pain. Morphine is used especially in pain associated with cancer, myocardial infarction and surgery. Morphine also helps to relieve the anxiety and insomnia which may be associated with severe pain.

Posology and Method of Administration

Adults and children over 12 years:

Morphine Sulfate Solution for Injection is formulated for use by the intravenous route in Patient Controlled Analgesia (PCA) systems. PCA, which permits adjustment of dosage according to the patient's individual needs, must only be carried out in departments and by staff who are trained and have experience of the system. Patient selection for the use of PCA must ensure that the patient is capable of understanding and following the instructions of the medical/nursing staff. The specific department or unit protocols must be covered to ensure aseptic transfer of the contents of the ampoule or vial to the PCA system.

There is a considerable variation in analgesic requirements among patients and therefore individualised treatment strategies are required. Dosage should be based on the severity of the pain and the response and opiate tolerance of the patient.

Loading Dose

Loading doses of typically between 1mg and 10mg (maximum 15mg) of morphine sulfate may be

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3. How to use Morphine Sulfate 1mg in 1mL Solution for Injection

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

The syringe may be put into a small machine which allows a slow continuous injection of this medicine to be given.

There is a procedure called Patient Controlled Analgesia (PCA) where you will be provided with a button to press when you are in pain and the machine will then give you a small amount of this medicine. There will be a safety device on the machine so that you cannot exceed the maximum number of doses.

Let your doctor or nurse know if your pain gets worse while you are using this medicine. Your doctor may want to increase your dose of the medicine and/or give you some extra medicines for the pain.

If you use more Morphine Sulfate 1mg in 1mL Solution for Injection than you should:

Tell your doctor as soon as possible. If you are a medical practitioner administering this medicine please refer to the Summary of Product Characteristics.

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 forget to use Morphine Sulfate 1mg in 1mL Solution for Injection.

The dose should be given as soon as it is remembered. The next dose should be given at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop using Morphine Sulfate 1mg in 1mL Solution for Injection

Tolerance and dependence are likely to occur after long-term treatment, and you may experience withdrawal symptoms if you stop taking this medicine suddenly. If you are concerned that you are becoming dependent on this medicine, speak to your doctor.

Do not stop treatment with Morphine Sulfate 1mg in 1mL Solution for injection unless agreed with your doctor. If you want to stop the treatment with Morphine Sulfate 1mg in 1mL 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 dissatisfaction, anxiety and irritability.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Important side effects or symptoms to look out for and what to do if you are affected:

- Serious allergic reaction which causes difficulty in breathing or dizziness.

If you are affected by these important side effects contact a doctor immediately

The most common side effects are respiratory depression (slow or shallow breathing), nausea, vomiting, constipation, feeling more sleepy than normal and feeling confused.

Other common side effects are:

- Muscle rigidity
- Inability to concentrate
- Itchiness
- Decreased effectiveness
- Hypothermia
- Disorientation
- Agitation
- Feeling of sadness
- Affected eye sight
- Upset stomach or indigestion
- Pain and irritation at the injection site
- Increased pressure inside the skull
- Rashes
- Affects normal sleep
- Sweating
- Abstinence symptoms or dependence (for symptoms see section 3: If you stop taking Morphine Sulfate 1mg in 1mL solution for injection).
- An increased sensitivity to pain
- Dry mouth
- Tachycardia (fast heartbeat)
- Postural hypotension (low blood pressure on sitting or standing)
- Spasm of the tubes of the kidney, bladder or gallbladder
- Vertigo
- Rash due to an allergic reaction in the skin
- Excitation
- Feeling of well being
- Dizziness
- Transient loss of consciousness
- Abdominal pain
- Feeling unwell
- Itchy rash of skin with raised bumps

Tell your doctor, nurse or pharmacist immediately if you think you have any of these, or other problems.

LONG-TERM TREATMENT WITH THIS MEDICINE

Further side effects can occur during long-term treatment with this medicine. These side effects include:

- Difficulty in urinating or unable to pass urine
- Hallucinations
- Colic
- Contractions of the pupils
- Dry mouth
- Restlessness
- Sweating/ facial flushing
- Mood changes
- Headache
- Decreased libido
- Palpitations
- Disruption of the menstrual cycle
- Slowed heartbeat
- Reduced blood pressure
- Spasm of the airways
- Changes in taste
- Fitting
- Recurrence of pancreatitis
- Uncontrolled movement of the eyes
- Fluid retention
- Increased blood pressure
- Loss of weight due to poor eating
- Total or partial bowel blockage
- Muscle jerk
- Muscle twitch
- Infertility
- Severe muscle pain
- Difficulty in coughing
- Depression
- Lack of strength in muscles
- Inability to obtain or sustain an erection of the penis
- Decreased effectiveness
- Increased sensitivity to the pain
- Reduced adrenal gland function

Reporting of Side Effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 1mg in 1mL Solution for Injection

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

This medicine has an expiry date printed on the ampoule or bottle (vial) and carton label. Before use the doctor or nurse will check the medicine has not passed this date and that the medicine does not show any sign of deterioration. The expiry date refers to the last day of the month.

After the expiry date return any unused medicine to a pharmacy.

Store this medicine away from sunlight and below 25°C.

6. Contents of the pack and other information

What Morphine Sulfate 1mg in 1mL Solution for Injection contains:

- The active substance is Morphine Sulfate at a strength of 1mg in 1mL.
- The other ingredients are Sodium Chloride and Water for Injections.

What Morphine Sulfate 1mg in 1mL Solution for Injection looks like and contents of the pack:

This medicine is a clear and colourless or almost colourless solution. This medicine is available in 1mL, 5mL and 10mL ampoules, and 50mL single use vials. The medicine is packed into cartons containing 10 ampoules, 1 vial or 10 vials. Both pack sizes of vials may not be available at the same time.

Marketing Authorisation Holder and Manufacturer:

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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.

Use in the elderly:

Morphine doses need to be reduced in elderly patients.

Incompatibilities

Morphine Sulfate Solution for Injection should not be mixed with other preparations.

Morphine salts are incompatible with aminophylline, sodium salts of barbiturates and phenytoin, aciclovir sodium, furosemide, heparin sodium, pethidine HCl, prochlorperazine edisylate and promethazine HCl.

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