

Morphine Sulfate 1 mg/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 your pharmacist.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

This medicine contains morphine which is an opioid, which can cause addiction.

You can get withdrawal symptoms if you stop taking it suddenly.

The name of your medicine is **Morphine Sulfate 1 mg/ml solution for injection**, which will be referred to as **Morphine Injection** throughout this leaflet.

What is in this leaflet

1. What Morphine Injection is and what it is used for
2. What you need to know before you use Morphine Injection
3. How to use Morphine Injection
4. Possible side effects
5. How to store Morphine Injection
6. Contents of the pack and other information

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

This medicine has been prescribed for you to relieve moderate to severe pain often caused by surgery, heart attack or cancer. Morphine also helps to reduce the anxiety and sleeplessness which may be caused by the pain.

Morphine Injection belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you use Morphine Injection

Do not use Morphine Injection if you:

- are allergic to morphine sulfate or any of the other ingredients in this medicine (listed in section 6)
- have a breathing disorder
- have a head injury or raised pressure around your brain
- have a convulsive disorder (epilepsy) or suffer from fits (seizures)
- have acute alcohol poisoning (intoxication)
- suffer from liver failure or kidney impairment
- suffer from biliary and renal tract spasm
- have an inflammation of your bowel or a bowel obstruction
- have Pheochromocytoma (a tumour of the adrenal gland)
- are taking any of the anti-depressant medicines known as monoamine oxidase inhibitors (MAOIs) or have taken them during the last two weeks
- are unconscious (coma)
- are at risk of a paralytic ileus (reduced gut motility)

Warnings and precautions

Talk to your doctor or nurse before using Morphine Injection if you:

- have low blood pressure
- have an under-active thyroid gland
- have asthma or other breathing difficulties
- have kidney or liver disorders
- suffer from an enlarged prostate gland
- suffer from decreased secretion of hormones
- have diabetes
- suffer from severe heart disease
- have irregular heart beat
- suffer from shock
- had a total joint arthroplasty
- have an adrenocortical insufficiency
- have diseases of the biliary tract
- have myasthenia gravis
- are pregnant or breast-feeding
- have stomach or bowel problems
- suffer from bad headaches or feel sick
- are elderly and/or debilitated
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.

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 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 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 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 Injection).

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering, or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

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The following information is intended for healthcare professionals only:

PREPARATION GUIDE:

Morphine Sulfate 1 mg/ml solution for injection

Please refer to the Summary of Product Characteristics for full prescribing and other information.

Therapeutic indications

Morphine sulfate injection is indicated for the relief of moderate to severe pain. Morphine sulfate injection 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.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Talk to your doctor or nurse if you experience any of the following symptoms while using Morphine Injection:

- 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 a hormone supplement.
- Loss of libido, impotence, cessation of menstruation. This may be because of decreased sex hormone production.

Acute generalized exanthematous pustulosis (AGEP) has been reported in association with Morphine 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 Injection or other opioids. Stop using Morphine 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 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.

Children

This medicine is not recommended for use in children under 12 years of age.

Other medicines and Morphine Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is especially important if you are taking any of the medicines mentioned below:

- Rifampicin to treat e.g. tuberculosis
- Concomitant use of Morphine 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 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.

- monoamine oxidase inhibitors – MAOIs (medicines used for depression) or if you have taken them during the last two weeks
- medicines that depress the nervous system (your doctor or pharmacist will know what these are)
- other painkillers – especially pentazocine, nalbuphine, or buprenorphine
- Gabapentin or pregabalin to treat epilepsy and pain due to nerve problems (neuropathic pain)
- muscle relaxants
- diuretics (water tablets) - medicines that increase urine excretion
- cimetidine – an anti-ulcer treatment
- disulfiram – a medication to treat chronic alcoholism
- antiarrhythmics - medicines to control heart rhythm or rate (e.g. mexiletine)
- ritonavir – a medicine to treat AIDS
- ciprofloxacin – an antibiotic
- medicines used to treat depression
- medicines used to treat anxiety
- medicines to help you sleep
- medicines for treatment of digestive tract disorders (e.g. cisapride)
- medicines used for Parkinson's Disease (selegiline)
- medicines used to treat vomiting or indigestion (e.g. domperidone or metoclopramide)
- anticholinergics (e.g. hyoscine)
- Some medicines used to treat blood clots (e.g. clopidogrel, prasugrel, ticagrelor) may have delayed and decreased effect when taken together with morphine

Morphine Injection and alcohol

Alcohol should be **avoided** during treatment with this medicine.

Pregnancy and breast-feeding

You should not be given Morphine Injection if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If Morphine Injection is used during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

You should not be given Morphine Injection while you are breastfeeding as morphine passes into breast milk and will affect your baby.

Driving and using machines

You must not drive or use machinery while receiving Morphine Injection.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while using 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 used 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

Morphine Injection contains sodium chloride

This medicine contains 35 mg sodium (main component of cooking/table salt) in each 10 ml ampoule.

This is equivalent to 2% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Morphine Injection

Your nurse or doctor will give you the injection.

Your doctor will decide the correct dosage for you and how and when the injection will be given.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Morphine 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 Injection, in this section).

Morphine Injection 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.

There is a procedure called Patient Controlled Analgesia (PCA) where you would be provided with a button to press when you are in pain and the machine would then give you a small amount of Morphine Injection. 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 Morphine Injection. 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 Injection than you should

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. 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 think you have been given too much, tell your doctor or nurse.

Tell your doctor or nurse immediately if any of the following symptoms of overdose occur:

- shallow breathing
- blue skin
- contraction of the pupils
- feeling extremely sleepy
- muscle weakness
- cold and clammy skin
- very slow heart rhythm
- fall in blood pressure

If you stop using Morphine Injection

Do not suddenly stop treatment with Morphine Injection unless agreed with your doctor. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

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

All medicines can cause allergic reactions, although serious allergic reactions are very rare.

Tell your doctor or nurse immediately if you experience any sudden difficulties in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have been reported:

• dependence and addiction (see section "How do I know if I am addicted?").	• coma
• feeling sick (nausea)	• low or high blood pressure
• vomiting	• spasms in the lung
• shallow breathing	• decreased ability to cough
• sleep apnoea (breathing pauses during sleep)	• problems with urination
• constipation	• impotence
• sleepiness	• swelling of the skin
• not knowing where you are (disorientation)	• feeling cold
• itching	• withdrawal symptoms. See 'Drug Withdrawal below.
• sweating	• drowsiness
• a perception of seeing or hearing things (hallucinations)	• confusion

• feeling of very intense happiness and well-being (euphoria)	• feeling of dizziness or "spinning" (vertigo)
• skin rash	• restlessness
• irregular skin patches and itching	• excitation
• pain at injection site	• tingling or numbness in the hands or feet (paraesthesia)
• headache	• feeling your heartbeat (palpitation)
• dizziness	• fainting (syncope)
• agitation	• upset stomach or indigestion
• fits	• total or partial bowel blockage
• impairment of taste	• loss of appetite (anorexia)
• mood changes	• abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis)
• high pressure in your brain (you may have a headache and feel sick or vomit)	• contraction of the tubes connecting the kidney and bladder (ureteric spasm)
• involuntary trembling and quivering	• disruption of the menstrual cycle
• muscle rigidity	• infertility
• contraction of the pupils	• decreased libido
• visual problems	• feeling of discomfort (malaise)
• dry mouth	• weakness
• stomach pain	• reduction of adrenal gland function
• gallbladder spasms with stomach pain	• 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
• facial flushing	• worsening of inflammation of your pancreas
• chills	• increased sensitivity to pain
• slow or fast heartbeat	• tolerance

Drug Withdrawal

When you stop receiving Morphine Injection, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst receiving Morphine Injection, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Injection

Do not store above 25°C. Keep the ampoules in the outer carton in order to protect them from light. The nurse or doctor will check that the injection is not past its expiry date and that the injection does not show any sign of deterioration before giving you the medicine.

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

6. Contents of the pack and other information

What Morphine Injection contains

The active substance is morphine sulfate. Each 1 ml of solution contains 1 mg of morphine sulfate.

The other ingredients are: sodium chloride, hydrochloric acid, water for injections.

What Morphine Injection looks like and contents of the pack

Morphine Injection is a sterile solution in a clear glass ampoule containing 10 ml.

Marketing Authorisation Holder

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This leaflet was last revised in September 2023.

46801/39/23

The following information is intended for healthcare professionals only: (Continued from overleaf)



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Incompatibilities

Morphine sulfate injection is physically incompatible with aciclovir sodium, aminophylline, amobarbital sodium, cefepime hydrochloride, chlorothiazide sodium, floxacillin sodium, furosemide, gallium nitrate, heparin sodium, meperidine hydrochloride, meperidine sodium, methicillin sodium, minocycline hydrochloride, pentobarbital sodium, phenobarbital sodium, phenytoin sodium, sargramostim, sodium bicarbonate, thiopental sodium.

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

Special precautions for storage

Do not store above 25°C. Keep the ampoules in the outer carton in order to protect from light.