

Package leaflet: Information for the user

Morphine Sulfate 10mg/ml and 30mg/ml Solution for Injection

Morphine Sulfate

(Referred to as Morphine Sulfate Injection in this leaflet)

Read all of this leaflet carefully before you are given 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, pharmacist or nurse.
- 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. See section 4.

What is in this leaflet

1. What Morphine Sulfate Injection is and what it is used for
2. What you need to know before you are given Morphine Sulfate Injection
3. How Morphine Sulfate Injection will be given
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1. What Morphine Sulfate Injection is and what it is used for

Morphine is an opioid analgesic with powerful pain relieving properties. This medicine is used for the relief of moderate to severe pain.

2. What you need to know before you are given Morphine Sulfate Injection

You should not be given Morphine Sulfate Injection if:

- you are allergic to Morphine Sulfate or any of the other ingredients of this medicine listed in section 6.
- 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 usually suffer from breathing difficulties (such as chronic obstructive airways disease) or you are currently having an asthma attack or difficulty breathing
- you are suffering from severe headaches or you have suffered a head injury
- you suffer from alcoholism
- you suffer from heart problems as a result of long term lung disease
- you are suffering from stomach pains or you have recently had abdominal surgery
- you are suffering from a tumour of the adrenal gland known as phaeochromocytoma
- you suffer from a condition causing bluish discolouration of the skin due to lack of oxygen in the blood
- you suffer or are currently suffering from fits
- you are suffering from a problem that could cause paralysis of the small intestine (paralytic ileus)
- you are in a coma

Warnings and precautions

Talk to your doctor, pharmacist or nurse before being given Morphine Sulfate Injection if:

- you suffer from low blood pressure
- you have severe asthma
- you have an under-active thyroid
- you suffer from shock
- you have kidney or liver problems
- you are prone to having fits

- you have low blood pressure and do not have enough blood in your body, which may make you feel lightheaded, faint, dizzy or have cold hands and feet
- you have swelling of the pancreas or bile duct problems
- you have poor adrenal gland function
- you have an enlarged prostate gland
- you have bowel problems (inflammatory bowel disorders)
- you have a heart problem after long-term lung disease (known as severe cor pulmonale)
- you are about to have an operation or have had one less than 24 hours ago
- you have an addiction to or a history of alcohol or drug abuse or you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking and sweating upon stopping taking alcohol or drugs
- you are elderly or are in poor state of health.
- you are taking any medicine from the group of
- medicines known as benzodiazepines.

Taking these medicines with Morphine Sulfate Injection may result in sedation, difficulties in breathing (respiratory depression), coma and may be fatal. Even if benzodiazepines are prescribed, your doctor may need to change the dose, the duration of treatment or monitor you regularly.

This product must be used with caution in newborn and premature babies.

Speak to your doctor if any of these apply to you before you are given this medicine.

Talk to your doctor, pharmacist or nurse if you experience any of the following symptoms while taking Morphine Sulfate 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 Morphine Sulfate 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.

Tolerance and dependence

Prolonged use of this medicine (one week or more) can result in mental and physical dependence on morphine. Repeated use can result in tolerance to morphine, meaning that you will need a higher dose to maintain the same level of pain relief. If you have any concerns regarding dependence or tolerance to morphine please talk to your doctor.

Other medicines and Morphine Sulfate Injection

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

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

- medicines that help you to sleep e.g. tranquilisers, hypnotics or sedatives (e.g. temazepam, diazepam, haloperidol and sulpiride)
- medicines to treat schizophrenia or other serious mental illness, such as phenothiazines (which may be present in various medicines including some for treating allergic disorders e.g. prochlorperazine, chlorpromazine and pipotiazine, promethazine)
- medicines to relax your muscles (e.g. baclofen, tizanidine)
- medicines to treat high blood pressure (e.g. methyldopa, moxonidine)
- gabapentin to treat epilepsy or pain due to nerve problems
- a general anaesthetic that makes you sleep, usually before an operation

- cimetidine (a medicine for ulcers, indigestion, or heartburn)
- ciprofloxacin (a type of antibiotic)
- another opioid painkiller (e.g. buprenorphine, nalbuphine, pentazocine)
- rifampicin (a medicine for tuberculosis)
- some medicines used to treat blood clots (e.g. clopidogrel, prasugrel, ticagrelor) may have delayed and decreased effect when taken together with opium
- ritonavir (a medicine to treat HIV)
- MAOIs used to treat depression (refer to “Do not take Morphine Sulfate Injection if” in section 2 above).
- 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 or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If you are given Morphine Sulfate Injection while you are in labour, your baby may have breathing problems. This medicine should not be administered to breast-feeding mothers.

If Morphine Sulfate 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.

Ask your doctor or pharmacist for advice before taking any medicine.

This medicine is not recommended for use whilst breast-feeding.

Effect on the ability to drive and use machines:

This medicine will cause drowsiness which could interfere with your ability to drive and operate machines. Do not drive or operate machinery if you feel drowsy or cannot think clearly. When your medicine treatment has stopped, ask your doctor when it will be safe for you to drive or use machines.

Having Morphine Sulfate Injection with alcohol

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

Morphine Sulfate Injection contains sodium and sodium metabisulfite (E223)

This medicine contains less than 1 mmol sodium (23mg) per ml, that is to say essentially ‘sodium-free.’ Also contains sodium metabisulfite which may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How Morphine Sulfate Injection will be given

This medicine is an injection and will be given to you by your doctor. Your doctor will determine the dose you need.

Morphine Sulfate Injection is administered either into a muscle, under the surface of the skin or into a vein. Under some circumstances your doctor may prescribe a dose higher than those stated here.

Adults

The usual adult dose for relief of pain by subcutaneous injection (an injection underneath the skin) or intramuscular injection (an injection into a muscle) is 10 to 15 mg every four hours, if necessary.

The dosage will be varied depending on your size and response to the drug.

Your doctor may give you a slow intravenous injection (an injection given slowly into a vein). The usual dose is 4 to 10mg, diluted in 4 to 5ml of Water for Injections over 4 to 5 minutes.

The elderly, patients with hepatic and renal impairment

If you are elderly, severely run down including feeling weak and feeble, or have liver and kidney problems the dose will be lower. You may also be given a reduced dose if you suffer from any of the conditions listed in section 2 entitled "Talk to your doctor before Morphine Injection is given to you if you:"

- Your doctor will decide the dose that is best for you. If you do not understand what you are being given, or are in any doubt, ask your doctor or nurse.

Children over 1 year

The usual dose is 0.1 to 0.2mg per kilogram of bodyweight into a muscle or under the skin every four hours up to a maximum of 15mg per dose.

Children under 1 year

Not recommended

If you are given too much of Morphine Sulfate Injection:

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

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

- difficulty in breathing
- pinpoint pupils
- low blood pressure
- fits, particularly in children
- development of a condition known as rhabdomyolysis, the symptoms of which include muscle pains, confusion, being sick and kidney failure
- fainting caused by your heart failing to pump blood around your body (circulatory failure)
- coma
- slow heart beat
- weakness or paralysis of the muscles

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 stop using Morphine Sulfate Injection

Do not stop treatment with Morphine Sulfate 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 dissatisfaction, anxiety and irritability.

4. Possible side effects

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

Serious side effects

- Any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body and paralytic Ileus (characterized by swollen belly,

fullness, gas, abdominal spasms, constipation, diarrhea, nausea with or without vomiting, and foul-smelling breath) should be reported to a doctor immediately.

The most serious side effect of Morphine Sulfate Injection is slowing of breathing or shallow breathing.

Common (may affect up to 1 in 10 people)

- Confusion, abnormal thoughts, difficulty in sleeping
- Headache, dizziness, muscle twitching or spasms, drowsiness
- Slowing of breathing or shallow breathing, decreased cough
- Pain or discomfort in the stomach or back, loss of appetite, stomach upset or indigestion, feeling sick (nausea) or being sick (vomiting), constipation, dry mouth
- Rash, sweating
- A feeling of unusual weakness, itching (Pruritus)
- Severe upper abdominal pain radiating to the back, nausea and vomiting which is worsened with eating (pancreatitis).
- Inappropriate eating habits, abnormal physical weakness or lack of energy

Uncommon (may affect up to 1 in 100 people)

- Mood changes, a feeling of extreme happiness or sadness, agitation, seeing or hearing things that are not there (hallucinations)
- Morphine when used repeatedly becomes habit forming (dependence on the drug)
- A feeling of dizziness or 'spinning' (vertigo), fits or convulsions, tingling in the hands and feet, fainting or loss of consciousness, stiff muscles
- Constriction of pupils of the eyes, blurred vision
- An unusually slow, fast or irregular heart beat
- High blood pressure, low blood pressure, redness of the face
- Accumulation of fluid in the lungs, slowing of breathing or shallow breathing
- Problems with your stomach, such as upset stomach, stomach cramps, constipation or not passing wind, a life-threatening condition of the intestine (colon) known as "Toxic Megacolon" which may be accompanied by a larger stomach area than normal, pain and fever or changes in taste
- Increase in liver enzymes
- Skin rash notable for pale red, raised, itchy bumps (urticaria)
- Difficulty in passing water or a severe, sharp pain on one or both sides of your lower back
- Absence of menstrual periods, decreased sexual drive, problems with erection
- Repeated use of the drug causes the drug to be less effective. When stopped suddenly causes withdrawal symptoms such as agitation, anxiety, shaking or sweating, feeling of discomfort or uneasiness, swelling of tissues due to accumulation of fluid.

Not Known: (frequency cannot be estimated from the available data)

- low body temperature
- Narcotic bowel Syndrome (chronic or frequently recurring abdominal pain)
- allodynia (Pain due to stimulus which does not normally provoke pain)
- hyperaesthesia (abnormal increase in sensitivity to stimuli such as touch, heat, cold)
- an increased sensitivity to pain
- sweating

If used during labour, Morphine Sulfate Injection can cause breathing difficulties in your newborn infant.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 16764971; Fax:+353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. How to store Morphine Sulfate 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 ampoule 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.

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

This medicine will not be used if it shows any signs of deterioration.

This medicine is for single use only. Your doctor or nurse will discard any remaining solution after the medicine has been given to you. Your doctor or nurse will give this medicine to you immediately after opening the ampoule.

6. Contents of the pack and other information

What Morphine Sulfate Injection contains:

The active ingredient: morphine sulfate.

Each ampoule contains 1%w/v (10mg in 1ml) or 3%w/v (30mg in 1ml) of morphine sulfate.

The other ingredients: sodium chloride, sodium metabisulfite and water for injections. This medicine may also contain sodium hydroxide solution or sulphuric acid solution.

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

Morphine Sulfate Injection is a Clear, colourless or almost colourless particle free solution, supplied in clear, colourless 1ml glass ampoules.

This medicine is supplied to your doctor in packs of 10 ampoules.

Marketing Authorisation Holder:

Ethypharm

194, Bureaux de la Colline, Bâtiment D 92213, Saint-Cloud Cedex, France

Manufacturer:

Martindale Pharma Ltd.

Bampton Road, Harold Hill, Romford, RM3 8UG, United Kingdom

Fannin Limited

Fannin House, South County Business park,

Dublin 18, D18 Y0C9,

Ireland

Marketing Authorisation Number(s):

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The following information is intended for healthcare professionals only:

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