Patient Information Leaflet Morphine Sulphate Injection BP
10 mg/ml, 15 mg/ml or 30 mg/ml. Solution for Injection Morphine Sulphate

Read all of this leaflet carefully before you are given this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- In this leaflet, Morphine Sulphate Injection BP 10 mg/ml, 15 mg/ml or 30 mg/ml Solution for Injection will be called Morphine Sulphate Injection.

In this leaflet:

1. What Morphine Sulphate Injection is for
2. Before you are given Morphine Sulphate Injection
3. How Morphine Sulphate Injection will be given to you
4. Possible side effects
5. How to store Morphine Sulphate Injection
6 Further information.

1. What Morphine Sulphate Injection is for

Morphine Sulphate Injection belongs to a group of medicines called narcotic analgesics which help relieve severe pain.

Morphine Sulphate Injection is for the treatment of severe pain, to help with breathing which becomes difficult because fluid has collected in the lungs (pulmonary oedema) due to heart failure. It can also be given prior to having an operation.

2. Before you are given Morphine Sulphate Injection

You must not be given Morphine Sulphate Injection if:

- You are allergic to morphine sulphate
- You are allergic to any of the other ingredients of Morphine Sulphate Injection (see section 6)
- You have conditions that make breathing difficult, such as obstructive airways disease, or your breathing is weak
- You are taking, or have recently taken (in the past two weeks) any drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs) e.g. phenelzine
- You have head injuries, headaches or have increased pressure in the skull (raised intracranial pressure)
- You have problems related to fluid on the brain (cerebral oedema)
- You suffer from convulsions (fits)
- You have severe stomach cramps (biliary colic)
- You have been drinking heavily or suffer from alcoholism
- You have a type of adrenal gland cancer called phaeochromocytoma
- You are at risk of having a blocked intestine (paralytic ileus)
- You have diarrhoea caused by poisoning or infection
- You are taking an antibiotic called ciprofloxacin
- You are pregnant or breast feeding
- You are a child.

Morphine sulphate is never given to patients in a coma.

If any of the above applies to you, do not use this medicine and talk to your doctor or nurse.

Check with your doctor before you are given Morphine Sulphate Injection if:

- You have low blood pressure (hypotension)
- You have an abnormally curved spine
- You are excessively over weight
- You have poor blood supply to the heart muscle or other heart problems
- You have asthma or other breathing problems such as emphysema
- You have sleep apnoea where your breathing is interrupted during sleep
- You have an under-active thyroid (hypothyroidism) or adrenal gland (adrenocortical insufficiency)
- You have liver or kidney disease
- You have a inflammatory or obstructive bowel disease such as Crohn's disease or ulcerative colitis
- You are in circulatory collapse (shock)
- You have difficulty passing water due to a narrowing of the tube that urine flows through from the bladder (urethral stricture)
- You are male and have an enlarged prostate or have difficulty passing water (prostatic hypertrophy)
- You have muscle weakness (myasthenia gravis)
- You have a tendency to abuse drugs or have ever suffered from drug abuse
- You are on a controlled sodium diet
- You are elderly.

If any of the above applies to you talk to your doctor or nurse.

Taking other medicines

- **You must not be given Morphine Sulphate Injection if you are taking, or have recently taken (in the past two weeks) any drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs), e.g. phenelzine**

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

- Drugs to help you sleep or reduce your anxiety (hypnotics and anxiolytics) e.g. diazepam
- Anticholinergic drugs to relax smooth muscle and regulate the heart rate e.g. atropine
- An antibiotic called ciprofloxacin
- Any other medicine, including medicines obtained without a prescription.

If any of the above applies to you talk to your doctor or nurse.

Pregnancy and breast-feeding

If you are pregnant, in labour or breastfeeding, Morphine Sulphate Injection will only be given to you if your doctor considers the benefit of treatment outweighs the risk to the infant foetus or new born baby.

If you are breastfeeding, your doctor or nurse will observe your baby for any side effects.

Driving and using machines

Morphine Sulphate Injection may cause drowsiness. If this happens to you, do not drive or use machinery.

Warnings about the ingredients

Morphine Sulphate Injection contains 0.24 mg of sodium per ml and may therefore not be suitable for you if you are on a controlled sodium diet. Tell your doctor or nurse before you are given Morphine Sulphate Injection if this applies to you.

Morphine Sulphate Injection contains sodium metabisulphite (E223) which may rarely cause severe allergic reactions and bronchospasm which can lead to difficulty in breathing.

3. How Morphine Sulphate Injection will be given to you

Important:
Morphine Sulphate Injection will be given to you by a doctor or nurse in hospital. Your doctor will choose the dose that is right for you.

Adults

- If this medicine is injected into a muscle or under the skin, the usual dose is 10 mg/ml every 4 hours.
- However, the amount may range from 5 mg to 20 mg depending on how severe your pain is and how you respond to the drug.
- If the drug is injected into a vein, the usual dose for an adult is 2.5 mg to 15 mg with at least 4 hours between doses.
- Your doctor or nurse may adjust the dose of your medicine and the number of injections you are given each day until your pain is relieved.

Elderly

Because this medicine can make breathing difficult, your doctor or nurse may reduce the dose of your medicine.

Children

Morphine Sulphate Injection is not for use in children.

If you think you have been given more Morphine Sulphate Injection than you should

As this medicine will be given to you whilst you are in hospital, it is unlikely that you will be given too little or too much, however, tell your doctor or nurse if you have any concerns.

Symptoms of serious overdose include breathing difficulties, low blood pressure with your heart finding it difficult to pump blood around your body, a deepening coma, feeling cold, fits especially in infants and children and rapid break down of muscle tissue progressing to kidney failure.

If you have these symptoms, you will be given another medicine called Naloxone to reverse the effects of Morphine Sulphate Injection.

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

4. Possible side effects

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

Seek immediate medical help if you have any of the following symptoms:

- Breathing difficulties
- Low blood pressure which may make you feel faint
- Your heart finding it difficult to pump blood around your body
- Allergic reactions causing:
- Swelling of hands, feet, lips, mouth, tongue or throat
- Difficulties breathing
- Itchy skin rash
- Diarrhoea or stomach pains.

The other side effects which have been reported are:

- Morphine is an addictive substance and its use can result in dependence, tolerance (reduced effect) and withdrawal symptoms (including moodiness and sleep disturbance)
- Changes in your heart beat, such as slowing or quickening of the heart beat. Also being aware that your heart is beating or the rate has changed.
- Low body temperature
- Raised pressure in the skull
- Seeing or hearing things that are not there
- Abdominal pain
- Very sensitive skin where you feel pain from a light touch
- Constriction of the pupil
- Blurred vision or uncontrolled eye movements
- A feeling of dizziness or “spinning”
- Head rush or dizzy spell
- Drowsiness and confusion
- An increase in liver enzymes
- Muscle twitching or rigidity with high doses
- Feeling sick or being sick
- Difficulty passing urine
- Headaches
- Constipation
- Changes of mood
- Decreased interest in sex or impotence
- Dry mouth
- Sweating
- Facial flushing (warmth and redness of the skin)
- Restlessness or fatigue
- Fits
- Rapid breakdown of muscle tissue
- Pain and irritation may occur at the site of the injection.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

5. How to store Morphine Sulphate Injection

Keep out of the reach and sight of children.

Do not use Morphine Sulphate Injection after the expiry date on the carton. The expiry date refers to the last day of that month.

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

Your doctor or nurse will make sure your medicine is correctly stored and disposed of.

6. Further information

What Morphine Sulphate Injection contains

The active substance is morphine sulphate 10 mg, 15 mg or 30 mg in each 1ml of solution.

The other ingredients are sodium metabisulphite (E223), sodium hydroxide, sulphuric acid and water for injections.

What Morphine Sulphate Injection looks like

Morphine Sulphate Injection is a sterile solution for injection in a clear glass container called an ampoule.

Morphine Sulphate Injection comes in cartons of 5 or 10 ampoules containing either 10 mg/ml, 15 mg/ml, 30 mg/ml and 60 mg/2 ml. Morphine Sulphate Injection also comes in ampoules attached to an adhesive vinyl label packed in cartons of 5 or 10 ampoules containing 10 mg/ml, 15 mg/ml or 300 mg/10ml packed in a carton of 1 ampoule. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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If this leaflet is difficult to see or read or you would like it in a different format, please contact UCB Limited, 208 Bath Road, Slough, Berkshire, SL1 3WE, UK.

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