PACKAGE LEAFLET: INFORMATION FOR THE USER

Morphine Sulfate 10mg/ml, 15mg/ml, 20mg/ml & 30mg/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 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

Morphine is an alkaloid with powerful pain relieving properties.
This medicine is used for the relief of severe pain.
It is also used to treat breathlessness caused by fluid in the lungs and as a pre-medication before operations.

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 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 suffer from breathing difficulties (asthma attack or chronic obstructive airways disease)
- you have suffered a head injury
- you suffer from alcoholism
- you suffer from heart problems
- you are suffering from stomach pains
- you are suffering from a tumour of the adrenal gland known as phaeochromocytoma
- you suffer from severe diarrhoea.

Warnings and precautions
Talk to your doctor or pharmacist before being given Morphine Sulfate Solution for Injection if you:
- suffer from low blood pressure
- suffer from underactive thyroid or adrenal gland
- suffer from problems with your prostate gland and have difficulty passing urine
- suffer from any liver or kidney diseases
- suffer from fits
- suffer from asthma
- have bowel disease, such as Crohn's disease or ulcerative colitis
- suffer from blockages of the bowel
- have problems with your bile duct

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 if you feel that you are becoming dependent on Morphine Sulfate 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.

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.
Please tell your doctor if you are taking any of the following medicines:
- 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 sleep (hypnotics) e.g. chloral and barbiturates
- medicines used to treat anxiety (anxiolytics) e.g. diazepam
- medicines used to treat bacterial infections e.g. ciprofloxacin and linezolid
- medicines used to control heart rhythm e.g mexiletine
- medicines used to treat pain e.g. pethidine
- medicines used in the treatment of Parkinson's disease e.g. selegiline
- medicines used to treat depression e.g. tricyclic antidepressants
- medicines used to treat mental illness including schizophrenia e.g. chlorpromazine, haloperidol
- medicines used to treat allergies, hay fever and asthma e.g. antihistamines
- medicines used to treat diarrhoea e.g. Loperamide, kaolin
- medicines used as premedication before operations and after heart attacks e.g. atropine
- medicines used to treat nausea and vomiting e.g. metoclopramide, domperidone
- rifampicin to treat e.g. tuberculosis
- 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.

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:
This medicine should not be used if you are pregnant, trying for a baby or breast-feeding. Morphine is known to cross the placenta.

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.

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.
- 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 and sodium metabisulfite (E223)

10 mg
This medicinal product contains 3.26 mg sodium per dose, equivalent to 0.16 % of the WHO recommended maximum daily intake of 2g sodium for an adult.

15 mg
This medicinal product contains 3.02 mg sodium per dose, equivalent to 0.15% of the WHO recommended maximum daily intake of 2g sodium for an adult.

20 mg
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'

30 mg
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'

The sodium metabisulfite may rarely cause severe hypersensitivity reactions and bronchospasm

3. How Morphine Sulfate Solution for 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.

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 10mg every four hours, if necessary. However, this can vary between 5mg and 20mg depending on your size and response to the drug.

For severe pain your doctor may give you a slow intravenous injection (an injection given slowly

into a vein). The usual dose is quarter to half of the intramuscular dose.

- 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.

If you are given too much of Morphine Sulfate Solution for 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.

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.

Tell your doctor or nurse immediately if you experience any of the following serious side effects:

- severe allergic reaction, with a rash, swelling of the eyes, lips and throat, and difficulty breathing
- fits
- physical and psychological dependence
- Serious allergic reaction which causes difficulty in breathing or dizziness.

Other side effects include:

- hallucinations (seeing or hearing things that aren't real)
- confusion
- mood changes
- headaches
- dizziness
- drowsiness
- sweating
- feeling faint when getting up from a seated position
- pinpoint pupils
- a fast, slow or irregular heartbeat
- feeling your heart beat (palpitations)
- facial flushing
- constipation
- feeling or being sick
- dry mouth
- spasms in the lower abdomen
- rashes and itching
- difficulty achieving or maintaining an erection
- difficulty in passing urine
- blurred vision
- stiff muscle
- pain irritation at injection site
- an increased sensitivity to pain
- abstinence symptoms or dependence (for symptoms see section 3: If you stop taking Morphine Sulfate Solution for Injection).

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 out of the sight and reach of children.

You should not be given Morphine Sulfate Solution for 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.

Keep the ampoule 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.
Each ampoule contains 10, 15, 20 or 30 mg morphine sulfate.
The other ingredients: sodium chloride, sodium metabisulfite (E223) and water for injections. This medicine may also contain sodium hydroxide solution or sulfuric acid solution.

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

Manufacturer:
Macarthys Laboratories
t/a Martindale Pharma
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Marketing Authorisation Holder:
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Product Licence Numbers:
PL 01883/6138. PL 01883/6176. PL 01883/6177.
PL 01883/6178

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Martindale Pharma

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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

D04080

D04080

100mm Measurement Verification Bar

4080-H

MARTINDALE PHARMA

DEVELOPMENT ARTWORK

Component Code: D04080

Prod: Morphine Sulfate 10mg/ml, 15mg/ml, 20mg/ml & 30mg/ml PIL UK PL 01883/6138. PL 01883/6176. PL 01883/6177. PL 01883/6178 Solution for Injection

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Version Control	Date	By
Version A :	29/11/17	NF
Version B:	22/01/18	NF
Version C:	20/03/18	NF
Version D:	24/04/18	NF
Version E:	25/04/18	NF
Version F:	26/04/18	NF
Version G:	01/07/19	SS
Version H:	10/09/19	NF
Version I:	12/09/19	NF
Version J:		
Version K:		
Version L:		
Version M:		
Version N:		
Version O:		

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