

Package leaflet: Information for the user**Morphine sulfate Kalceks 10 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 nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

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2. What you need to know before you are given Morphine sulfate Kalceks
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1. What Morphine sulfate Kalceks is and what it is used for

Morphine is one of a group of medicines called opioid analgesics, which are used to relieve moderate to severe pain.

Morphine is used for the relief of severe pain and it is also used to treat breathlessness caused by fluid in the lungs and as a pre-medication before operations in adults.

2. What you need to know before you are given Morphine sulfate Kalceks**Do not use Morphine sulfate Kalceks if you:**

- are allergic to active substance or any of the other ingredients of this medicine (listed in section 6);
- have conditions that make breathing difficult, such as obstructive airways disease or your breathing is weak;
- are taking, or have recently taken (in the past two weeks) any drugs for depression known as monoamine oxidase inhibitors (MAOIs);
- have head injuries, headaches or have increased pressure in the skull (raised intracranial pressure);
- have problems related to fluid on the brain (cerebral oedema);
- suffer from convulsions (fits);
- have severe stomach cramps caused by a condition known as biliary colic;
- are suffering from acute alcoholism;
- suffer from antibiotic induced pseudomembranous colitis;
- have ulcerative colitis;
- have been told you have a tumour of the adrenal gland near your kidney called phaeochromocytoma;
- are at risk from a blocked intestine (paralytic ileus);
- are suffering from severe diarrhoea caused by food poisoning or an infection.

Morphine sulfate 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.

Warnings and precautions

Talk to your doctor or nurse before you are given Morphine sulfate Kalceks, if you:

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- have low blood pressure (hypotension);
- have a disease that causes difficulty in breathing as asthma, emphysema, cor pulmonale (high blood pressure causing failure of the right side of the heart), abnormal spinal shape and excessive obesity;
- have an under-active thyroid (hypothyroidism) or adrenal gland (adrenocortical insufficiency);
- have a liver or kidney disease;
- have an inflammatory or obstructive bowel disease such as Crohn`s disease or ulcerative colitis;
- are in circulatory collapse (shock);
- are male and have an enlarged prostate or have difficulty passing water (prostatic hypertrophy);
- have muscle weakness (myasthenia gravis);
- have biliary disorders;
- have a tendency to abuse drugs or have ever suffered from drug abuse;
- are elderly.

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

- 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 Kalceks 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.

Children

This medicine is not recommended for use in children.

Other medicines and Morphine sulfate Kalceks

Tell your doctor if you are taking have recently taken or might take any other medicines. In particular, tell your doctor if you are taking any of the following:

- monoamine oxidase inhibitors (MAOIs) such as moclobemide or phenelzine used in the treatment of depression;
- tricyclic antidepressants, which are used in the treatment of depression;
- tranquillising drugs or sleeping tablets such as diazepam, nitrazepam and temazepam;
- medicines used to treat mental illnesses, including schizophrenia (e.g. chlorpromazine, haloperidol);
- medicines used for diarrhoea (e.g. loperamide, kaolin);
- medicines which are used as premedication before operations and after heart attacks such as atropine;
- medicines used to treat nausea and vomiting, such as metoclopramide or domperidone;
- mexiletine, used to control heart rhythm;
- some antihistamines, used to treat allergies, hay fever and asthma;
- certain antibiotics, used to treat infections (e.g. ciprofloxacin and linezolid);
- selegiline, used in the treatment of Parkinson`s disease;
- pethidine, used to treat pain;
- cimetidine, used as anti-ulcer drug;
- rifampicin to treat e.g. tuberculosis;
- ritonavir, used in the treatment of HIV;
- some medicines used to treat blood clots (e.g. clopidogrel, prasugrel, ticagrelor) may have delayed and decreased effect when taken together with morphine;
- concomitant use of Morphine sulfate Kalceks 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 Kalceks

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.

Morphine sulfate Kalceks with alcohol

You should not drink alcohol whilst being given Morphine sulfate Kalceks, as it will increase its effects.

Pregnancy and breast-feeding

If you are pregnant, in labour or breastfeeding, Morphine sulfate Kalceks 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. Morphine may reduce contractions during labour, cause breathing problems to the infant foetus or new-born baby and affect the heart rate of the foetus. If Morphine sulfate Kalceks 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.

If you are breast-feeding, ask your doctor for advice before using this medicine.

Driving and using machines

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

Morphine sulfate Kalceks contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per one ml.

3. How Morphine sulfate Kalceks will be given to you

Morphine sulfate Kalceks will be given to you by a doctor or nurse in hospital. Your doctor will choose the dose that is right for you.

Adults

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

As this medicine make breathing difficult, your doctor or nurse may reduce dose of your medicine.

Use in children

Morphine sulfate Kalceks is not recommended for use in children.

Hepatic impairment

A reduction in dosage should be considered in hepatic impairment.

Renal impairment

The dosage should be reduced in moderate to severe renal impairment.

If you think you have been given more Morphine sulfate Kalceks 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.

Overdose may cause pneumonia from inhaling vomit or foreign matter, symptoms may include breathlessness, cough and fever. Symptoms of serious overdose include breathing difficulties leading to unconsciousness or even death, 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 (characterized by dark coloured urine and muscle tenderness, stiffness or aching) progressing to kidney failure.

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

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

If you stop using Morphine sulfate Kalceks

Do not stop treatment with Morphine sulfate Kalceks unless agreed with your doctor. If you want to stop the treatment with Morphine sulfate Kalceks, ask your doctor how to slowly decrease the dose 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.

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

- Breathing difficulties (respiratory depression)
- Low blood pressure (hypotension) which may make you feel faint
- Your heart finding it difficult to pump blood around your body (circulatory failure) causing faintness, breathing difficulties, coughing up blood, excessive sweating and/or pale skin
- Serious allergic reaction which causes:
 - Swelling of hands, feet, lips, mouth, tongue or throat
 - Difficulty in breathing or dizziness
 - Itchy skin rash (hives)
- Stomach pains, bloating, vomiting and constipation (obstructive bowel disorder)

The other side effects which have been reported are:

Very common (may affect more than 1 in 10 people):

- Seeing or hearing things that are not there (hallucinations)
- Morphine is an addictive substance and its use can result in dependence
- Drowsiness and confusion
- Feeling (nausea) or being sick (vomiting)
- Constipation
- Sweating
- The drug no longer having the same effect as it used to (drug tolerance)

Common (may affect up to 1 in 10 people):

- Changes in your heart beat, such as slowing (bradycardia) or quickening (tachycardia) of the heart beat
- Low body temperature (hypothermia)
- Raised pressure in the skull (increased intracranial pressure)
- Abdominal pain (biliary spasms)
- Constriction of the pupil (miosis)
- Blurred vision
- Involuntary eye movements (nystagmus)
- A feeling of dizziness or “spinning”(vertigo)
- Dizziness/light headedness on standing (orthostatic hypotension)
- Difficulty passing urine
- Headaches
- Changes of mood

- Decreased libido (interest in sex) or inability to get an erection
- Dry mouth
- Facial flushing (warmth and redness of the skin)
- Restlessness
- Fits (convulsions)
- Increased sensitivity to pain
- Tiredness (fatigue)
- Stopping the drug can lead to withdrawal symptoms such as agitation, anxiety, shaking or sweating. This can also happen to babies born to mothers addicted to morphine.
- Pain and irritation may occur at the site of the injection

Uncommon (may affect up to 1 in 100 people):

- Being aware that your heart is beating or the rate has changed (palpitations)
- Abdominal pain (urethral spasms)
- An increase in liver enzymes may be noted during blood tests

Not known (cannot be estimated from the available data):

- Muscle stiffness with high doses
- Pain, generally on the skin, caused by something that would not normally cause pain such as light touch or pressure
- Coma
- Kidney failure
- Abstinence symptoms or dependence (for symptoms see section 3: If you stop using Morphine sulfate Kalceks)

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Morphine sulfate Kalceks

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

Store below 25 °C. Protect from light.

Product containing visible particles should not be used.

Do not use this medicine after the expiry date which is stated on the carton after {abbreviation used for expiry date}. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Morphine sulfate Kalceks contains

- The active substance is morphine sulfate 10 mg in each 1 ml of solution.
- The other ingredients are sodium chloride, hydrochloric acid (for pH adjustment), water for injections.

What Morphine sulfate Kalceks looks like and contents of the pack

Clear colourless or almost colourless solution for injection.

Morphine sulfate Kalceks 10 mg/ml is presented in 1 ml amber glass ampoules with white open point cut. The ampoules are packed in liners. The liners together with leaflets are packed in cartons.

Pack size: 10 ampoules.

Marketing Authorisation Holder

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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 sulfate and 5-fluorouracil.

Instruction of ampoule opening:

- 1) Turn the ampoule with coloured point up. If there is any solution in the upper part of the ampoule, gently tap with your finger to get all the solution to the lower part of the ampoule.
- 2) Use both hands to open; while holding the lower part of the ampoule in one hand, use the other hand to break off the upper part of the ampoule in the direction away from the coloured point (see the pictures below).

