

## **Package leaflet: Information for the user**

### **Morfin Kalceks 10 mg/ml solution for injection**

morphine hydrochloride trihydrate

**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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What Morfin Kalceks is and what it is used for**

Morfin Kalceks contains the active substance morphine and belongs to a group of medicines called natural opium alkaloids. This medicine is used to relieve severe pain, when other pain relieving medicines do not have sufficient effect.

#### **2. What you need to know before you use Morfin Kalceks**

##### **Do not use Morfin Kalceks:**

- if you are allergic to morphine hydrochloride trihydrate or any of the other ingredients of this medicine (listed in section 6)
- in conditions with a lot of mucus in the airways
- in impaired breathing function
- in acute liver disease
- in anxiety conditions in patients affected by alcohol or sleeping medicines

##### **Warnings and precautions**

There is a risk of being addicted to Morfin Kalceks.

Talk to your doctor, pharmacist or nurse before using Morfin Kalceks if you:

- are addicted to other pain-relieving medicines (opioids)
- receive peritoneal dialysis
- have asthma
- have airway cramps
- have skull injuries
- have low blood pressure with reduced blood volume
- have impaired thyroid function
- have impaired liver or kidney function
- have inflammatory bowel disease
- have inflammation of pancreas
- have bile or urinary tract cramps
- have enlarged prostate gland
- have muscular weakness called myasthenia gravis
- have concomitant treatment with MAO inhibitors (medicine to treat depression)

Talk to your doctor, pharmacist or nurse if you experience any of the following symptoms while using Morfin 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 Morfin 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.

#### 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 Morfin Kalceks 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 Morfin Kalceks 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 using Morfin Kalceks, 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 using Morfin Kalceks).

In the treatment of elderly patients a lower dose of Morfin Kalceks is recommended.

This medicine should not be used in the pain treatment of unknown origin or in pain connected with mental disorders.

Acute generalized exanthematous pustulosis (AGEP) has been reported in association with Morfin Kalceks 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 Morfin Kalceks or other opioids. Stop using Morfin Kalceks and seek medical attention immediately, if you notice any of the following symptoms: blistering, widespread scaly skin or pus-filled spots together with fever.

This medicine should not be administered alone during biliary or kidney colic attacks as it may increase the cramp. In these cases Morfin Kalceks should be given in a combination with spasms relieving medicine (spasmolytic).

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.

The effects of this medicine can be enhanced after encephalitis (inflammation of the brain).

**Sleep-related breathing disorders:** Morfin Kalceks 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.

### **Other medicines and Morfin Kalceks**

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:

- rifampicin to treat e.g. tuberculosis;
- 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 Morfin 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 Morfin 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.

The effect of the treatment can be affected if Morfin Kalceks is taken concomitantly with certain other medicines.

#### *Combinations that should be avoided with Morfin Kalceks:*

- tranquilizers and sleeping pills containing barbiturates (methohexital, penthotal, phenobarbital);
- medicines to treat depression or Parkinson's disease (MAO inhibitors) (moclobemide, selegiline).

These medicines can decrease breathing function if used in combination with Morfin Kalceks.

#### *Medicines that may require dose adjustment:*

- medicines to treat epilepsy and pain due to nerve problems (neuropathic pain) (gabapentin, pregabalin);
- medicines to treat depression (clomipramine, amitriptyline, nortriptyline);
- some other pain relieving medicines (buprenorphine, nalbuphine, pentazocine).

#### *Other medicines that can affect or be affected by Morfin Kalceks:*

- antispasmodic medicines (baclofen);
- tranquilizers containing benzodiazepines (nitrazepam, flunitrazepam, tirazolam, midazolam);
- tranquilizers that reduces itching (hydroxyzine);
- medicines stimulating the central nervous system (methylphenidate);
- medicines against brain membrane bleeding (nimodipine);
- medicines to treat HIV (ritonavir).

### **Morfin Kalceks with alcohol**

The combination with alcohol should be avoided since the breathing function can deteriorate.

### **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.

#### *Fertility*

When studied in animals, this medicine has shown adverse effects on animal fertility and may cause damage to the developing foetus. Therefore, women of childbearing potential, and men, should use effective contraceptive measures. Please discuss this with your doctor.

#### *Pregnancy*

If Morfin 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. The use of morphine during labour may cause impaired breathing function in the new-born baby.

#### *Breast-feeding*

Morphine passes into the breast milk. Morfin Kalceks should therefore not be used during breast-feeding.

### **Driving and using machines**

You must not drive or use machinery while receiving Morfin Kalceks. The medicine can affect your ability to react.

### **Morfin Kalceks contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per ml of solution, that is to say essentially 'sodium-free'.

## **3. How to use Morfin Kalceks**

Always use this medicine exactly as your doctor or pharmacist has told you. Ask your doctor or pharmacist if you are not sure.

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

The dose is individual and is determined by your doctor. It depends on your age, weight, pain severity and previous medication and pains.

#### *Elderly*

A lower dose will be prescribed.

#### *Hepatic and renal impairment*

A lower dose will be prescribed.

The dose may need reduction in patients with bronchial asthma, upper respiratory tract obstruction, skull injuries, peritoneal dialysis, hypotension associated with hypovolemia, hypothyroidism, inflammatory bowel diseases, pancreatitis, biliary passage or ureter spasms. Medicine can be administered intravenously, intramuscularly or subcutaneously.

### **If you use more Morfin Kalceks than you should**

If you have received too much medicine or for instance if a child took the medicine by mistake, you should seek medical advice. Symptoms of overdose are: pinpoint pupils, low blood pressure, breathing difficulties leading to unconsciousness or even death. People who have taken an overdose may get

pneumonia from inhaling vomit or foreign matter, symptoms may include breathlessness, cough and fever. Circulatory disorders and coma can occur in serious cases.

### **If you forget to use Morfin Kalceks**

Do not take a double dose to make up for a forgotten dose.

### **If you stop using Morfin Kalceks**

Withdrawal symptoms can occur if you suddenly stop using Morfin Kalceks or if you use certain other strong pain relieving medicines.

Do not stop treatment with Morfin Kalceks unless agreed with your doctor. If you want to stop the treatment with Morfin 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 unsatisfaction, anxiety and irritability.

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

## **4. Possible side effects**

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

Impaired breathing function is a serious, uncommon side effect with morphine, which may affect up to 1 of 100 people. If you have trouble breathing, immediately contact a doctor for treatment of the impaired breathing function.

Contact a doctor **immediately** if you have:

- a serious allergic reaction which causes difficulty in breathing or dizziness.
  - 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).

*Common (may affect up to 1 in 10 people):* drowsiness, dizziness, narrowed pupils, nausea, vomiting, constipation, difficulties in urinating, increase in ADH (a hormone) release.

*Uncommon (may affect up to 1 in 100 people):* depressed mood, confusion, spasm in the airways, spasm in the urinary or bile duct, itching, light-headedness.

*Rare (may affect up to 1 in 1000 people):* palpitations, rapid heartbeat (tachycardia), fainting, dizziness when rapidly standing up, high blood pressure, low blood pressure, swollen feet and legs.

*Not known (frequency cannot be estimated from the available data):* euphoria (sense of happiness), sleep, memory and concentration disturbances, spasm, sleep apnoea (breathing pauses during sleep), dry mouth, 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), nettle rash, involuntary muscle twitches (myoclonus), an increased sensitivity to pain, sweating, abstinence symptoms or dependence (for symptoms see section 3: If you stop using Morfin Kalceks).

### **Reporting of side effects**

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

## **5. How to store Morfin Kalceks**

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

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.

Store in the original package in order to protect from light.

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 Morfin Kalceks contains**

- The active substance is morphine hydrochloride trihydrate.
- Morfin Kalceks contains 10 mg/ml morphine hydrochloride trihydrate equivalent to 7.6 mg/ml morphine.
- The other ingredients are sodium chloride, hydrochloric acid concentrated (for pH adjustment), water for injections.

### **What Morfin Kalceks looks like and contents of the pack**

1 ml clear, colourless or yellowish solution for injection in colourless glass ampoules (type I).  
Pack size: 10 ampoules.

### **Marketing Authorisation Holder and Manufacturer**

[To be completed nationally]

### **This medicine is authorised in the Member States of the European Economic Area under the following names:**

|                  |                                                     |
|------------------|-----------------------------------------------------|
| Sweden:          | Morfin Kalceks, 10 mg/ml, injektionsvätska, lösning |
| The Netherlands: | Morfine Kalceks 10 mg/ml, oplossing voor injectie   |
| Poland:          | Morphine Kalceks                                    |
| Czech Republic:  | Morphine Kalceks                                    |
| Hungary:         | Morphine Kalceks 10 mg/ml oldatos injekció          |
| Portugal:        | Morfina Kalceks                                     |
| Slovakia:        | Morphine Kalceks                                    |
| Spain:           | Morfina Kalceks 10 mg/ml solución inyectable EFG    |

### **This leaflet was last revised in**

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