

Package leaflet: Information for the patient

Morphine Unimedic 1 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, pharmacist 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, 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 Unimedic is and what it is used for
2. What you need to know before you are given Morphine Unimedic
3. How Morphine Unimedic is given
4. Possible side effects
5. How to store Morphine Unimedic
6. Contents of the pack and other information

1. What Morphine Unimedic is and what it is used for

Morphine Unimedic contains the active substance morphine hydrochloride which has a substantial analgesic effect.

Morphine Unimedic is used for severe pain such as cancer pain and for pain relief after surgery or injuries after external violence.

2. What you need to know before you are given Morphine Unimedic

You should not be given Morphine Unimedic:

- if you are allergic to morphine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- in conditions with much mucous in the airways
- in conditions of inhibited breathing
- in acute liver disease
- in states of uneasiness (agitation) occurring in patients affected by alcohol or hypnotics

Warnings and precautions

There is a risk for addiction with Morphine Unimedic. To avoid side effects when treatment is no longer needed the dose may need to be gradually lowered.

Talk to your doctor, pharmacist or nurse before receiving Morphine Unimedic if you have:

- an addiction to other pain killers (opioids)
- asthma
- head injury
- low blood pressure with decreased blood volume
- impaired thyroid function
- hepatic or renal impairment
- inflammatory bowel disease
- inflammation of the pancreas
- spasm of the bile ducts or ureters

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

- 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.

In the treatment of elderly a lower dose of Morphine Unimedic is recommended due to an increased risk of inhibited breathing.

As constipation is a common side effect, you may need to use laxatives at the same time you are given Morphine Unimedic.

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

Sleep-related breathing disorders

Morphine Unimedic 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.

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.

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 Morphine Unimedic 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 Morphine Unimedic 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 taking Morphine Unimedic, 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 taking Morphine Unimedic).

Children and adolescents

All children, especially new borns, are at risk for developing breathing problems with this medicine, The doctor will give morphine with special caution to children below one year of age.

Other medicines and Morphine Unimedic

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Pay special attention to:

- tranquilizers and sleeping pills (barbiturates, e.g. methohexital, pentothal, phenobarbital, meprobamate)
- medicines to treat depression (clomipramine, amitriptyline, nortriptyline and MAO inhibitors such as moclobemide,)
- medicine to treat Parkinsons disease (selegiline)
- some other analgesics (buprenorphine, nalbuphine, pentazocine, diclofenac).
- medicine to treat tuberculosis (rifampicin)
- Some medicines used to treat blood clots (e.g. clopidogrel, prasugrel, ticagrelor) may have delayed and decreased effect when taken together with morphine
- medicines to treat epilepsy and pain due to nerve problems such as neuropathic pain (gabapentin or pregabalin)
- some antihypertensives (clonidine)
- Concomitant use of Morphine Unimedic 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 Unimedic 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 Unimedic with alcohol

Morphine Unimedic may cause inhibition of breathing during concomitant use with even small amounts of alcohol. Concomitant use of Morphine Unimedic and alcohol should therefore be avoided.

Pregnancy and breast-feeding

Men or women of childproducing/childbearing potential should not receive Morphine Unimedic unless birth control is used.

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, tell your doctor before being given this medicine.

Morphine Unimedic should not be given during pregnancy unless the doctor decides the benefit for the mother is higher than the risk to the baby. If Morphine Unimedic 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 breathing problems for the newborn baby. It may also change the length of labour.

Breast-feeding

Morphine is excreted into breast milk. Morphine Unimedic should not be used during breast-feeding.

Driving and using machines

The effect and possible side effects of Morphine Unimedic has major influence on the ability to drive and use machines. Ask your doctor for advice when it is safe to drive and use machines

3. How Morphine Unimedic is given

This medicine will be given by health care professionals with appropriate training and experience. Your doctor will decide on the dose appropriate for you.

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

If you receive more Morphine Unimedic than you should

Morphine Unimedic will be given to you under supervision by health care professionals. If you are worried that you have received more of the medicinal product than you should tell your doctor or nurse. Symptoms of overdose include: pin-point pupils, inhibited breathing, low blood pressure and you may get pneumonia from inhaling vomit or foreign matter, symptoms may include breathlessness, cough and fever. Circulatory disorders and coma may occur in severe cases. People who have taken an overdose may also have breathing difficulties leading to unconsciousness or even death.

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

If you stop using Morphine Unimedic

Do not stop treatment with Morphine Unimedic unless agreed with your doctor. If you want to stop the treatment with Morphine Unimedic, 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.

4. Possible side effects

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

If you are affected by the following side effect contact a doctor immediately and stop taking the medication:

- Serious allergic reaction which causes difficulty in breathing or dizziness. Frequency *Not known (frequency cannot be estimated from the available data)*.
- 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). Frequency *Not known (frequency cannot be estimated from the available data)*.

Other side effects

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

- drowsiness
- pupil reduction,
- nausea, vomiting, obstipation

- problems passing urine
- increased ADH (a hormone) release
- itching

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

- depressed mood
- inhibition of breathing, spasm in the airways
- spasm in ureter or bile duct
- itching
- lightheadedness

Rare (may affect up to 1 in 1,000 people):

- dizziness when rapidly rising up
- rapid, strong, or irregular heartbeat
- rapid heart rate
- high or low blood pressure
- swollen feet and legs
- fainting

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

- exhilaration
- sleep, memory and concentration disorders
- seizures
- dry mouth
- hives
- muscle twitching
- experiencing or seeing things which do not exist, confusion
- An increased sensitivity to pain
- Sweating
- Abstinence symptoms or dependence (for symptoms see section 3: If you stop using Morphine Unimedic)
- Sleep apnoea (breathing pauses during sleep)
-

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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist 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](#) listed in [Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Morphine Unimedic

Morphine Unimedic should be used immediately after opening.

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 EXP. The expiry date refers to the last day of that month.

Keep the ampoule in the outer carton, in order to protect from light.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What Morphine Unimedic contains

- The active substance is morphine hydrochloride trihydrate.
1 ml solution for injection contains 1 mg morphine hydrochloride trihydrate corresponding to 0.76 mg morphine.

10 ml solution for injection contains 10 mg morphine hydrochloride trihydrate corresponding to 7.6 mg morphine.
- The other ingredients are sodium chloride and water.

What Morphine Unimedic looks like and contents of the pack

10 ml clear solution in clear glass ampoules in packages of 10 ampoules.

Marketing Authorisation Holder and Manufacturer

Unimedic Pharma AB
Box 6216
10234 Stockholm
Sweden

This leaflet was last revised in 23 January 2024

The following information is intended for healthcare professionals only:

Before subcutaneous and intramuscular doses corresponding to very small volumes are administered to a new born child Morphine Unimedic should be diluted to avoid dosing errors. Isotonic sodium chloride solution should be used. Dilution corresponding to an administration volume above 2 ml should be avoided.

For epidural use it is appropriate, with customary techniques, to ensure that the administration of morphine occurs in the epidural space. Both the effect and the risk of undesirable effects are significantly strengthened if Morphine Unimedic accidentally is administered intrathecally.

Splashes on the skin and in the eyes can cause pain, redness and itching. Avoid direct contact with the medicinal product.

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

Symptoms and treatment of overdose:

Symptoms of overdose include pin-point pupils, respiratory depression and hypotension. Circulatory disorders and coma may occur in severe cases.

Typical triad symptoms: low level of consciousness, severe respiratory depression, maximum miotic pupils. Hypotension. Pale, clammy skin. At high doses, cyanosis, areflexia, respiratory arrest, unconsciousness, circulatory failure, pulmonary oedema. Acidosis, convulsions (especially in children), possibly hypokalaemia and hypocalcaemia. Nausea, vomiting, constipation. Risk of

myocardial injury, rhabdomyolysis and renal failure in severe intoxication.

Treatment of overdose: Respiratory depression at morphine intoxication can be reversed with naloxone, initially 0.4 mg for adults (children 0.01 mg/kg) slowly intravenously, the dose is gradually increased if necessary.

Continuous infusion of naloxone can sometimes be a practical option.

Respiratory treatment on the indication (with PEEP in pulmonary edema). Naloxone cannot replace respiratory therapy in serious intoxication.

Intravenous fluids (electrolyte, glucose), blood gas control, acidosis correction. Symptomatic therapy.