

Package leaflet: Information for the user

Morfin Abcur 10 mg/ml, solution for injection morphine hydrochloride

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 Abcur is and what it is used for
2. What you need to know before you use Morfin Abcur
3. How to use Morfin Abcur
4. Possible side effects
5. How to store Morfin Abcur
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1. What Morfin Abcur is and what it is used for

Morfin Abcur is a medicine used to relieve severe pain, and it belongs to a group of medicines called natural opium alkaloids.

2. What you need to know before you use Morfin Abcur

Do not use Morfin Abcur:

- 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 reduced breathability
- in acute liver disease
- in states of uneasiness in patients affected by alcohol or hypnotics

Warnings and precautions

There is a risk of habituation with Morfin Abcur.

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 Abcur 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 Abcur 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 Morfin Abcur, 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).

Talk to your doctor or pharmacist before using Morfin Abcur if you have:

- an addiction to other pain killers (opioids)
- asthma
- airway cramps
- 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
- enlarged prostate gland
- muscle weakness called myasthenia gravis
- 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 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.

Acute generalized exanthematous pustulosis (AGEP) has been reported in association with Morfin Abcur 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 Abcur or other opioids. Stop using Morfin Abcur 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

Morfin Abcur 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.

In treatment of elderly a lower dose of Morfin Abcur is recommended.

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

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

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

Other medicines and Morfin Abcur

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If Morfin Abcur is taken simultaneously with certain other medicines, the effect of treatment may be affected.

A large number of drugs can interact with Morphine Sulfate Injection which can significantly alter their effects. E.g. gabapentin or pregabalin to treat epilepsy and pain due to nerve problems (neuropathic pain).

Morfin Abcur may cause impaired respiratory function during concomitant use with:

- tranquilizers and sleeping pills (methohexital, pentothal, phenobarbital, meprobamate)
- medicines to treat depression (MAO inhibitors) (moclobemide, selegiline)

The effect of Morfin Abcur is enhanced by:

- tranquilizers and sleeping pills (methohexital, pentothal, phenobarbital)
- medicines to treat depression (clomipramine, amitriptyline, nortriptyline)
- MAO inhibitors (moclobemide, selegiline)

The effect of Morfin Abcur decreases when co-administered with some other analgesics (buprenorphine, nalbuphine, pentazocine).

During concomitant therapy with rifampicin (to treat e.g. tuberculosis), the dose of Morfin Abcur may need to be increased.

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 Abcur 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 Abcur 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.

Morfin Abcur with food, drink and alcohol

Combination with alcohol should be avoided since the respiratory function may be impaired.

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

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.

If Morfin Abcur is used for a long time during pregnancy there is a risk of the newborn child having drug withdrawal (abstinence) symptoms which should be treated by a doctor. The use of morphine during labour may cause reduced respiratory function in the newborn baby.

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

Driving and using machines

Treatment with Morfin Abcur may impair the ability to react. This should be considered when alertness is required, eg when driving or operating machinery.

3. How to use Morfin Abcur

Always use this medicine exactly as your doctor or pharmacist has told you. Check with 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 Abcur, 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 Abcur, in this section).

Dosage is individual and determined by the doctor.

Adults:

The usual dose is 1- 1.5 ml solution for injection given subcutaneously or intramuscularly 1-3 times daily. In urgent cases, morphine can be given slowly intravenously.

Elderly:

A lower dose is recommended in elderly patients.

Use in patients with liver or kidney problems

A lower dose is recommended in patients with liver or kidney problems.

If you use more Morfin Abcur than you should

If you have taken more medicinal product than you should or if for example a child has taken the medicine by mistake, you should seek medical advice. People who have taken an overdose may get pin point pupils, low blood pressure and in severe cases circulatory disorders and 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, coma or even death.

If you forget to use Morfin Abcur

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

If you stop using Morfin Abcur

Do not stop treatment with Morfin unless agreed with your doctor. If you want to stop the treatment with Morphin, ask your doctor how to slowly decrease the dosis 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 or pharmacist.

4. Possible side effects

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

Stop taking Morfin Abcur and contact a doctor or go to the nearest emergency department immediately if you experience the following symptoms:

- Difficulty beathing. This could be a sign of respiratory depression (impaired breathing function) (uncommon side effect).
- 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).

If you notice any of the following, contact your doctor immediately:

- chronic or frequently recurring abdominal pain sometimes also with nausea, vomiting, bloating feeling and constipation (these could be signs of a condition known as narcotic bowel syndrome). The frequency of this reaction is not known (frequency cannot be estimated from available data).

Other side effects that may occur:

Common (may affect up to 1 in 10 people)

- drowsiness
- pupil reduction
- nausea
- vomiting
- constipation
- problems passing urine
- increase in ADH release (a hormone that causes the body to retain water and dilute the blood, reducing the amount of sodium)
- spasm in the airways

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

- depressed mood
- spasm in ureter or bile duct
- itching
- dizziness
- light-headedness

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

- dizziness when rapidly rising up

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

- agitation
- dry mouth
- fits (seizures)
- itchy rash (nettle rash)

- increased sensitivity of your skin
- increased sensitivity to pain
- tingling sensation of your skin (paresthesia)
- excessive sweating
- abstinence symptoms or dependence (for symptoms see section 3: If you stop taking Morfin Abcur)
- palpitations, slow heart beat, fast heart beat
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store Morfin Abcur

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.

Do not store above 25°C. Keep the ampoule in the outer carton, 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 Abcur contains

- The active substance is morphine hydrochloride.
- 1 ml contains 10 mg morphine hydrochloride corresponding to 7.6 mg morphine.
- 5 ml contains 50 mg morphine hydrochloride corresponding to 37.95 mg morphine
- The other ingredients are hydrochloric acid, water for injections.

What Morfin Abcur looks like and contents of the pack

Morfin Abcur, solution for injection (injection), is a clear solution.

1 ml in clear glass ampoules in packages of 5 or 10 ampoules.

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

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised in June 2026

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.