

MORPHINE MEDIS® 10 mg/mL, solution for injection

Chlorhydrate de morphine

Read all of this leaflet carefully before 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 also any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet ?

1. What is MORPHINE MEDIS10 mg/mL, solution for injection and in which case it is used ?
2. What you need to know before you take MORPHINE MEDIS 10 mg/mL, solution for injection?

3. How to take MORPHINE MEDIS 10 mg/mL, solution for injection ?
4. Possible side effects?

5. How to store MORPHINE MEDIS10 mg/mL, solution for injection?

6. Content of the packaging and other information.

1. WHAT IS MORPHINE MEDIS 10 mg/mL, solution for injection AND IN WHICH CASE IS IT USED ?

Pharmacotherapeutic Class: OPIOID ANALGESIC. ATC code: N02AA01.

This medication is recommended for the treatment of severe pain when weaker analgesics are insufficient.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MORPHINE MEDIS 10 mg/mL, solution for injection ?

Never take MORPHINE MEDIS 10 mg/mL, solution for injection:

- if you are allergic to morphine hydrochloride or any of the other ingredients of this medicine (listed in section 6);

- if you suffer from severe respiratory failure,

- if you have severe liver disease,

- if you have uncontrolled epilepsy,

- if you have a recent head injury,

- in combination with buprenorphine, nalbuphine, pentazocine and naltrexone (substances with properties comparable to those of morphine),

- during breastfeeding in the event of initiation or continuation after birth of long-term treatment

Contraindications related to epidural, intrathecal and intraventricular routes

- Coagulation disorder at the time of the act,

- Local skin infections, regional or general, in progress,

- Progressive intracranial hypertension.

If in doubt, it is essential to seek the advice of your doctor or pharmacist.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using MORPHINE MEDIS 10 mg / mL, solution for injection.

Due to its concentration, the presentation in 10 mL ampoule is intended for patients undergoing morphine treatment and particularly suitable for continuous administration techniques in adults. Your doctor will accompany this treatment with monitoring adapted to its use.

In the event of prolonged treatment with morphine, it is imperative not to suddenly stop the treatment, as this exposes the occurrence of a withdrawal syndrome.

The gradual increase in doses, when necessary and even if they are high, does not expose to the risk of development of addiction.

This medicine, when misused, can cause physical and psychological dependence.

Drug addition, past or current, does not prevent the prescription of morphine if it is necessary. Talk to your doctor, pharmacist or nurse if you experience any of the following symptoms while using MORPHINE MEDIS 10 mg / mL, solution for injection:

Increased sensitivity to pain despite taking increasing doses (hyperalgesia). Your doctor will decide whether a change in dose or a switch to a strong analgesic ("pain reliever") is necessary (see section 2);

Weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. These symptoms may indicate that the adrenal glands are making too little of the hormone cortisol and that you need to take a hormone supplement.

Loss of libido, impotence, amenorrhea (absence of menstruation). These symptoms may indicate a decrease in the production of sex hormones ;

If you have a history of alcoholism or drug abuse. Also report if you think you are becoming dependent on MORPHINE MEDIS 10 mg / mL, solution for injection while using it. You may often think about your next dose, although it is not necessary : Symptoms of withdrawal or addiction. The most common withdrawal symptoms are listed in section 3. If this happens, your doctor may change the type of medicine or the intervals between doses.

This medication should be used with caution :

- in the elderly,

- in infants,

- in patients with respiratory failure,

- in patients with renal failure,

- in patients with hepatic impairment,

- in case of insufficient blood volume (hypovolaemia),

- in case of difficulty urinating,

- in case of high pressure in the skull,

- in case of constipation (report any constipation to your doctor for appropriate treatment).

Alcohol intake is strongly discouraged.

Other medicines and MORPHINE MEDIS 10 mg / mL, solution for injection

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is especially important if you are taking any of the medicines listed below or medicines for the following purposes :

Naltrexone or morphine agonist-antagonists (buprenorphine, nalbuphine, pentazocine) ;

Rifampicin to treat, for example, tuberculosis ;

Concomitant use of MORPHINE MEDIS 10 mg / mL solution for injection and sedative medicines such as benzodiazepines or related medicines increases the risk of drowsiness, breathing difficulties (respiratory depression) and coma, and can be life-threatening. Therefore, concomitant use should only be considered if there are no other treatment options. However, if your doctor prescribes MORPHINE MEDIS 10 mg / mL, solution for injection in combination with sedative medicines, he or she should take care to limit the dose and the duration of the concomitant treatment. Tell your doctor about all sedative medications you are taking and strictly follow their dosage recommendations. It may be helpful to let your friends or family know about the signs and symptoms listed above. Contact your doctor if you have such symptoms.

MORPHINE MEDIS10 mg/mL, solution for injection with food, drinks and alcohol

Alcohol intake is strongly discouraged.

If in doubt, do not hesitate to seek the advice of your doctor or pharmacist.

Pregnancy and breastfeeding

Pregnancy

The use of morphine, if necessary and after advice from your doctor, is possible during pregnancy. Due to the passage of this medication into the bloodstream of the fetus, its use during pregnancy requires special monitoring of the child.

If MORPHINE MEDIS 10 mg / mL solution for injection is used for long-term during pregnancy, there is a risk that the newborn baby will have withdrawal symptoms which should be treated by a doctor.

Breastfeeding

- a single dose appears to be safe for the newborn,

- in the event of repeated administration over a few days, temporarily suspend breastfeeding,

- in the event of initiation or continuation after the birth of a long-term treatment, breastfeeding is contraindicated.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby,

ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Attention is drawn, particularly among vehicle drivers and machine users, to the risks associated with the possible decrease in vigilance induced by this medicine, particularly at the start of treatment and in the event of combination with other medicines.

MORPHINE MEDIS 10 mg/mL, solution for injection contains sodium

Each mL of solution for injection contains 2.95 mg sodium, equivalent to 0.13 mmol sodium. Each 1 mL ampoule contains 2.95 mg sodium, equivalent to 0.13 mmol sodium.

This medicine contains less than 1 mmol (23 mg) sodium per ampoule, that is to say essentially « sodium-free ».

3. HOW TO USE MORPHINE MEDIS 10 mg/mL, solution for injection ?

Dosage

In all cases, strictly comply with the medical prescription.

Method of administration :

Injectable route : subcutaneous or intravenous or epidural or intrathecal

In all cases, strictly comply with the medical prescription.

Frequency of administration

In all cases, strictly comply with the medical prescription.

Duration of treatment

Do not stop taking this medicine without your doctor's advice. In all cases, strictly comply with the medical prescription.

Incompatibilities :

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

Morphine solutions should not be mixed with alkaline or iodine solutions, aminophylline, heparin, chlorothiazide salt, methicillin salts, nitrofurantoin salts.

If you use more MORPHINE MEDIS 10 mg / mL, solution for injection than you should

People who take too much may develop pneumonia caused by inhaling vomiting or foreign matter ; symptoms may include shortness of breath, cough, and fever.

People who take too much may also have difficulty breathing leading to unconsciousness or even death.

In case of overdose or accidental poisoning, call a doctor urgently.

If you forget to use MORPHINE MEDIS 10 mg / mL, solution for injection

Seek your doctor's advice.

If you stop using MORPHINE MEDIS 10 mg / mL, solution for injection

Do not interrupt treatment with MORPHINE MEDIS 10 mg / mL, solution for injection without your doctor's consent. If you want to stop taking MORPHINE MEDIS 10 mg / mL, solution for injection ask your doctor how to gradually reduce the dose to avoid the onset of withdrawal symptoms. Withdrawal symptoms may include the following : body aches, tremors, diarrhea, abdominal pain, nausea, flu-like symptoms, rapid heartbeat and dilated pupils. Psychological symptoms include intense feelings of dissatisfaction, anxiety and irritability.

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

4. POSSIBLE SIDE EFFECTS ?

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

Important symptoms and side effects to watch out for and what to do if any :

- serious side effects causing difficulty in breathing or dizziness.

If you experience any of these important side effects, contact a doctor immediately.

The most common side effects are :

- drowsiness, confusion, nausea and vomiting, which are transient,

- constipation which must be prevented by appropriate treatment.

Adverse reactions with unknown frequency :

- sedation, excitement, nightmares, especially in the elderly, with possibly hallucinations

- (abnormal perception of an object that does not exist in reality),

- increased intracranial pressure resulting in headaches or even vomiting,

- urinary retention in case of prostate problems or urethral stricture,

- dry mouth,

- spasms,

- respiratory depression,

- physical dependence,

- sometimes skin reactions such as hives, redness, itching,

- increased sensitivity to pain,

- sweating,

- withdrawal symptoms or dependence (for symptoms see section 3. If you stop taking

- MORPHINE MEDIS 10 mg / mL, solution for injection »),

- severe skin reactions.

Reporting Side Effects

If you get any side effects talk to your doctor, pharmacist or nurse. This also applies to any side effects that are not mentioned in this leaflet. You can also report side effects directly via the national reporting system : CNPP (Centre National de Pharmacovigilance).

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MORPHINE MEDIS 10 mg/mL, solution for injection ?

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 package after EXP.

The expiration date refers to the last day of that month.

Keep the immediate packaging in the outer packaging in order to protect from light.

After opening, the product should be used immediately.

A slight yellow coloration of the solution does not affect the quality or effectiveness of the medicine

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

6. CONTENT OF THE PACKAGING AND OTHER INFORMATION

What MORPHINE MEDIS10 mg/mL, solution for injection contains

- The active substance is :

Morphine hydrochloride 10,00 mg

For 1 mL of solution for injection. One ampoule of 1 mL contains 10 mg of morphine hydrochloride.

- The other components are :

Sodium chloride, sodium hydroxide, hydrochloric acid, water for injections.

Marketing Authorization Holder and Manufacturer

Les laboratoires MEDIS

Road of Tunis Km 7 - PB 206 Nabeul 8000 - Tunisia.

Tel : +216.72.235.006

Fax : +216.72.235.016

E-mail : contact@labomedis.com

Supply Conditions : Table B – Narcotic ; only by prescription

M.A. N° :

MORPHINE MEDIS 10mg/mL, solution for injection ampoule of 1mL box of 10 : 9234031H

This leaflet was last reviewed : September 2019

This is a Medicine

- A medicine is a product but not like any other product.

- A medicine is a product that affects your health. If it's not used properly ; it can be health threatening.

- Strictly adhere to the prescription of your Doctor and the use instructions prescribed, follow your pharmacist advice.

- Your doctor and your pharmacist know the medicine, its use and side effect.

- Don't stop the use of the treatment on your own during the prescribed time.

- Don't retake, don't increase the doses without doctor's advice.

Keep all medicine out of reach of children

