

Remifentanil Médís® 1mg
Remifentanil Médís® 5mg
Powder for solution for injection or infusion
Remifentanil Hydrochloride

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Remifentanil Médís is and what it is used for
2. Before you take Remifentanil Médís
3. How you take Remifentanil Médís
4. Possible side effects
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1. What Remifentanil Médís is and what it is used for?

Pharmacotherapeutic group:

Remifentanil Médís contains a medicine called remifentanil. This belongs to a group of medicines known as opioids.

Therapeutic indications:

Remifentanil Médís is used together with other medicines called anaesthetics

- to help put you to sleep before an operation
- to keep you asleep and stop you feeling pain during an operation
- to make you feel sleepy and stop you feeling pain while you receive treatment in an Intensive Care Unit.

2. Before you take Remifentanil Médís:

a- Do not take Remifentanil Médís:

- If you are allergic (hypersensitive) to remifentanil or any of the other ingredients of Remifentanil Médís (see section 6)
- If you are allergic (hypersensitive) to any other opioid medicines, such as morphine, codeine, alfentanil or fentanyl.

If you are not sure if any of the above apply to you, talk to your doctor, health care provider or pharmacist before having Remifentanil Médís.

b- Take special care with Remifentanil Médís:

Check with your doctor or pharmacist before having Remifentanil Médís:

- If you are over 65 years of age
- If you are dehydrated or have lost a lot of blood
- If you have been feeling weak or unwell
- If you are overweight

If you are not sure if any of the above apply to you, talk to your doctor, health care provider or pharmacist before treatment with Remifentanil Médís.

c- Taking other medicines, herbal or dietary supplements

In particular tell your doctor or pharmacist if you are taking:

- medicines for your heart or blood pressure, such as beta-blockers (these include atenolol, metoprolol, carvedilol, propranolol and bisoprolol) or calcium channel blockers (these include amlodipine, diltiazem and nifedipine).

Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

This includes herbal medicines. This is because Remifentanil Médís can work with other medicines to cause side effects.

d- Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby,

ask your doctor, for advice before having this medicine.

e- Driving and using machines

If you are only staying in hospital for the day, your doctor will tell you how long to wait before leaving the hospital or driving a car. It can be dangerous to drive too soon after having an operation.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - o The medicine has been prescribed to treat a medical or dental problem and
 - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and

o It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

3. How you take Remifentanil Médís

How Remifentanil Médís, is given

You will never be expected to give yourself this medicine. It will always be given to you by a person who is qualified to do so.

Remifentanil Médís can be given:

- as a single injection into your vein
- as a continuous infusion into your vein. This is where the drug is slowly given to you over a longer period of time.

The way you are given the drug and the dose you receive will depend on:

- your weight
- the operation you have
- how much pain you will be in
- how sleepy the medical staff want you to be in the Intensive Care Unit.

The dose varies from one patient to another.

a- If you take Remifentanil Médís more than you should

The effects of Remifentanil Médís are carefully monitored throughout your operation and in intensive care, and appropriate action will be taken promptly if you receive too much.

After your operation

Tell your doctor or health care provider if you are in pain. If you are in pain after your procedure, they will be able to give you other painkillers.

4. Possible side effects

Like all medicines, Remifentanil Médís can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Some people can be allergic to Remifentanil Médís. You must tell your doctor or health care provider immediately if you have:

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

- sudden wheeziness and chest pain or chest tightness
- swelling of your eyelids, face, lips, mouth or tongue
- a lumpy skin rash or 'hives' anywhere on the body
- collapse.

Tell your doctor as soon as possible if you notice any of the following:

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

- muscle stiffness
- low blood pressure
- feeling sick or being sick

Common (may affect up to 1 in 10 people)

- slow heartbeat
- shallow breathing or temporarily stop breathing
- itching

Uncommon (may affect up to 1 in 100 people)

- problems breathing (hypoxia)

- constipation

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

- allergic reactions

- heart stops beating

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

• physical need for Remifentanil Médís (drug dependency) or the need for increasing doses over time to get the same effect (drug tolerance)

- fits (seizures)
- a type of irregular heartbeat (atrioventricular block)

Other side effects that can happen when you wake up after having an anaesthetic include:

Common (may affect up to 1 in 10 people)

- shivering
- increases in blood pressure
- Uncommon (may affect up to 1 in 100 people)**
- aches

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

- feeling very calm or drowsy (sedation)

Other side effects which occurred particularly upon abrupt cessation of Remifentanil Médís after prolonged administration of more than 3 days

- Heart beating faster (tachycardia)
- High blood pressure (hypertension)
- Restlessness (agitation).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

5. How to store Remifentanil Médís

Keep out of the sight and reach of children.

- Store at a temperature below 25 °C
- Store in the original package with this leaflet.

Reconstituted solution is chemically and physically stable at 24 hours at 25°C.

Do not use Remifentanil Médís after the expiry date which is stated on the vial and carton. The expiry date refers to the last day of that month.

Do not use Remifentanil Médís if you notice that the solution is not clear limpid, colourless and contain insoluble particles and the lyophilisat does not dissolve completely.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

Shelf life: 24 months

6. Further information

a- What Remifentanil Médís contains:

Remifentanil Médís 1 mg

• The active substance is Remifentanil Hydrochloride 1 mg

Remifentanil Médís 5 mg

• The active substance is Remifentanil Hydrochloride 5 mg

• The other ingredients are: Glycine, hydrochloric acid or sodium hydroxide.

b- What Remifentanil Médís looks like and contents of the pack:

Remifentanil Médís, powder for solution for injection or infusion is a sterile, Hydrophilic compact cake powder and it is available in the following strengths:

- Remifentanil Médís 1mg, in type I glass vials

- Remifentanil Médís 5mg, in type I glass vials

The powder will be mixed with an appropriate fluid before being injected.

Each strength of Remifentanil Médís is supplied in cartons containing 5 vials.

c- Marketing Authorisation Holder and Manufacturer:

LES LABORATOIRES MEDIS - S.A.

Road of Tunisia - KM 7 - BP 206 - 8000 Nabeul - Tunisia

Tel : (216) 72 23 50 06. Fax: (216) 72 23 50 16.

E-mail : contact@labomedis.com

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

Salehiya Trading Establishment

(Medical equipment & pharmaceuticals)

P.O.Box: 991, Riyadh 11421- Kingdom of Saudi Arabia

Tel: 00 966 1 46 46 955

Fax: 00 966 1 46 34 362

a- This leaflet was last approved in "April 2015"; version number " 00"

b- To report any side effect(s):

• Saudi Arabia:

- The National Pharmacovigilance and Drug Safety Centre (NPC)
 - o Fax: +966-11-205-7662
 - o Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340
 - o Toll free phone: 8002490000
 - o E-mail: npc.drug@sfd.gov.sa
 - o Website: www.sfd.gov.sa/npc

• Other GCC states:

- Please contact the relevant competent authority.

c- Council of Arab Health Ministers

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 you 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 the medicines out of reach of children