Remifentanil 1 mg / 2 mg / 5 mg
powder for concentrate for solution for injection/infusion

xxxxxx

xxxxxxx/48/24

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

hameln

Remifentanil 1 mg powder for concentrate for solution for injection/infusion
Remifentanil 2 mg powder for concentrate for solution for injection/infusion
Remifentanil 5 mg powder for concentrate for solution for injection/infusion

Remifentanil (as hydrochloride)

Read all of this leaflet carefully before you are given 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 Remifentanil is and what it is used for

Remifentanil belongs to a group of medicines called opioids. It differs from other medicines in this group by its very quick onset and very short duration of action.
- Remifentanil may be used to stop you feeling pain before or while you are having an operation.
- Remifentanil may be used to relieve pain while you are under controlled mechanical ventilation in an Intensive Care Unit (for patients 18 years of age and over).

2. What you need to know before you are given Remifentanil

You should not be given remifentanil
- if you are allergic to remifentanil, any of the other ingredients of this medicine (listed in section 6) or fentanyl derivates (such as alfentanil, fentanyl, sufentanil). An allergic reaction may include rash, itching, difficulty of breathing or swelling of the face, lips, throat or tongue.
- as injection into the spinal canal
- as sole medicine to initiate anaesthesia

Warnings and precautions

Talk to your doctor before you receive remifentanil if:
- you ever had any adverse reactions during an operation
- you ever had any allergic reactions or if you have been told that you are allergic to:
  - any medicines used during an operation
  - opioid medicines (e.g. morphine, fentanyl, pethidine, codeine), see also section **"You should not be given remifentanil"** above**.**
- you suffer from impaired lung and/or liver function (you may be more sensitive to breathing difficulties)
- you or anyone in your family have ever been dependent on opioids, 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.
- you are over 65 years of age
- you are dehydrated or have lost a lot of blood
- you have been feeling weak or unwell
- you are overweight

This medicine contains remifentanil which is an opioid medicine. Repeated use of opioid painkillers may result in the drug being less effective (you become accustomed to it). It may also lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on remifentanil, it is important that you consult your doctor.
Withdrawal reactions including rapid heartbeat, high blood pressure and restlessness have occasionally been reported when treatment with this medicine is stopped suddenly, particularly when treatment has lasted more than 3 days (see also section 4. Possible side effects). If you experience these symptoms, your doctor may re-introduce the medicine and gradually reduce the dose.
If you are not sure if any of the above apply to you, talk to your doctor, pharmacist or nurse before you are given remifentanil.

Other medicines and Remifentanil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines you can get without a prescription. This is especially important with the following medicines as they may interact with remifentanil:
- Medicines for your heart or blood pressure, such as beta-blockers (these include atenolol, metoprolol, carvedilol, propanolol and bisoprolol) or calcium channel blockers (these include amlodipine, diltiazem and nifedipine). These medicines may increase the effect of remifentanil on your heart (lowering of your blood pressure and your heart beat).
- Medicines for the treatment of depression such as Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin Norepinephrine Reuptake Inhibitors (SNRIs) and Monoamine Oxidase Inhibitors (MAOIs). It is not recommended to use these medicines at the same time as remifentanil as they may increase the risk of serotonin syndrome, a potentially life-threatening condition.

Sedatives such as benzodiazepines or related medicines

Concomitant use of remifentanil and sedative medicines such as benzodiazepines or related medicines 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. The concomitant use of opioids and drugs used to treat epilepsy, nerve pain or anxiety (gabapentin and pregabalin) increases the risk of opioid overdose, respiratory depression and may be life-threatening.
However, if your doctor does prescribe remifentanil together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

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.

Children

Remifentanil is not recommended in newborn infants and infants (children under the age of one year).
There is little experience of use of remifentanil to treat children in intensive care units.

Remifentanil with alcohol

After having received remifentanil you should not drink alcohol until fully recovered.

Pregnancy and breast-feeding

You should not be given Remifentanil if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.
If you are given this medicine during labour or close to childbirth, it can affect your baby's breathing. You and your baby will be monitored for signs of excessive sleepiness and difficulty breathing.
If you are given Remifentanil during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.
Remifentanil should not be given to pregnant women unless medically justified. Remifentanil is not recommended during labour or a Caesarean section.
You should not be given Remifentanil while you are breastfeeding as Remifentanil passes into breast milk and will affect your baby. It is recommended that you stop breast-feeding for 24 hours after remifentanil has been given to you.

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:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - 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 Remifentanil is given

Remifentanil must only be given under carefully controlled conditions and emergency equipment has to be available. This medicine will be given by or under the supervision of an experienced doctor who is familiar with the use and action of the type of medicine.
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 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 following information is intended for healthcare professionals only:

PREPARATION GUIDE FOR

hameln

Remifentanil 1 mg powder for concentrate for solution for injection/infusion
Remifentanil 2 mg powder for concentrate for solution for injection/infusion
Remifentanil 5 mg powder for concentrate for solution for injection/infusion

Please refer to the Summary of Product Characteristics for full prescribing and other information.

It is important that you read the entire contents of this guide prior to the preparation of this medicinal product.

Reconstitution

Remifentanil should be prepared for intravenous use by adding the appropriate volume (as stated in the table below) of one of the below listed diluents to give a reconstituted solution with a concentration of approximately 1 mg/ml.

Presentation	Volume of diluent to be added	Concentration of the reconstituted solution
Remifentanil 1 mg	1 ml	1 mg/ml
Remifentanil 2 mg	2 ml	1 mg/ml
Remifentanil 5 mg	5 ml	1 mg/ml

Shake until completely dissolved. The reconstituted solution should be clear, colourless and free of visible particles.

Further Dilution

After reconstitution, Remifentanil must not be used without further dilution to concentrations of 20 to 250 micrograms/ml with one of the injection solutions listed below (50 micrograms/ml is the recommended dilution for adults and 20 to 25 micrograms/ml for paediatric patients aged 1 year and over).
For target-controlled infusion (TCI) the recommended dilution of Remifentanil is 20 to 50 micrograms/ml.
The dilution is dependent upon the technical capability of the infusion device and the anticipated requirements of the patient.
One of the following solutions should be used for dilution:
- Water for Injections
- Glucose 50 mg/ml (5 %) solution for injection
- Glucose 50 mg/ml (5 %) solution for injection and sodium chloride 9 mg/ml (0.9 %) solution for injection
- Sodium chloride 9 mg/ml (0.9 %) solution for injection
- Sodium chloride 4.5 mg/ml (0.45 %) solution for injection

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.

If you receive more Remifentanil than you should or if you miss a dose of Remifentanil
Since remifentanil will usually be given to you by a doctor or nurse under carefully controlled conditions, it is unlikely that you will be given too much or that you will miss a dose.

If you have received too much of this medicine, or if it is suspected, that you may have received too much, appropriate action will be taken promptly by your healthcare specialist team.

After your operation

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

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.

The following side effects have been reported:

Very common (may affect more than 1 in 10 people)
- muscle stiffness
- feeling sick (nausea) or being sick (vomiting)
- low blood pressure (hypotension)

Common (may affect up to 1 in 10 people)
- slow heart beat (bradycardia)
- shallow breathing (respiratory depression)
- respiratory arrest (apnoea)
- itching
- shivering after the operation
- high blood pressure (hypertension) after the operation
- cough

Uncommon (may affect up to 1 in 100 people)
- constipation
- pain after the operation
- oxygen deficiency (hypoxia)

Rare (may affect up to 1 in 1,000 people)
- slow heartbeat with subsequent cardiac arrest in patients who receive remifentanil together with one or more anaesthetics
- sleepiness (during recovering from the operation)
- severe allergic reactions including shock, circulatory failure and heart attack in patients who receive remifentanil together with one or more anaesthetics

Not known (frequency cannot be estimated from the available data)
- fits (seizures)
- a type of irregular heartbeat (atrioventricular block)
- irregular heartbeat (arrhythmia)
- cardiac arrest
- drug tolerance
- dependence and addiction (see section “How do I know if I am addicted?”).
- withdrawal syndrome (may manifest by the occurrence of the following side effects: increased heart rate, high blood pressure, feeling restless or agitated, nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating)

How do I know if I am addicted?
If you notice any of the following signs whilst receiving remifentanil, it could be a sign that you have become addicted.
- You need to receive the medicine for longer than advised by your prescriber
- You feel you need to receive more than the recommended dose
- You are receiving the medicine for reasons other than prescribed
- When you stop receiving the medicine you feel unwell, and you feel better once receiving the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Remifentanil

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 and label after “EXP.”. The expiry date refers to the last day of that month.
Do not store above 25°C.
Do not use this medicine if you notice the solution is not clear and free of particles or if the container is damaged.
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 to protect the environment.

6. Contents of the pack and other information

What Remifentanil contains
The active substance is remifentanil.
Remifentanil 1 mg
One vial contains remifentanil hydrochloride equivalent to 1 mg remifentanil.
Remifentanil 2 mg
One vial contains remifentanil hydrochloride equivalent to 2 mg remifentanil.
Remifentanil 5 mg
One vial contains remifentanil hydrochloride equivalent to 5 mg remifentanil.
After reconstitution as directed each ml solution for injection/infusion contains 1 mg remifentanil.
The other ingredients are glycine and hydrochloric acid (for pH-adjustment).

What Remifentanil looks like and contents of the pack
Remifentanil is a white to off-white or yellowish powder for concentrate for solution for injection/infusion (powder for concentrate). It is supplied in colourless glass vials.
Pack size per strength:
5 vials per pack
Not all pack sizes may be marketed.

Marketing Authorisation Holder
hameln pharma ltd
Nexus, Gloucester Business Park
Gloucester, GL3 4AG
United Kingdom

Manufacturer
hameln rds s.r.o.
Horná 36
900 01 Modra
Slovakia

This leaflet was last revised in 11/2024.

xxxxxx/48/24

The following intravenous fluids may also be used when administered into a running IV catheter:
• Lactated Ringer's Injection
• Lactated Ringer's and glucose 50 mg/ml (5 %) solution for injection
Remifentanil is compatible with propofol when administered into a running IV catheter.
No other diluents should be used.
The solution is to be inspected visually for particulate matter prior to administration. The solution should only be used if the solution is clear and free from particles.
Ideally, intravenous infusions of Remifentanil should be prepared at the time of administration.
Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C.
From a microbiological point of view, the medicinal product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.
The content of the vial is for single use only. Any unused product or waste material should be disposed of in accordance with local requirements.

Special precautions for storage
Do not store above 25°C.
For storage conditions after reconstitution/dilution of the medicinal product, see section **Further Dilution**.