

Remifentanil APOTEX

Contains the active ingredient remifentanil (as hydrochloride)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about remifentanil. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Remifentanil APOTEX powder for injection. It contains the active ingredient remifentanil (as hydrochloride).

Remifentanil is an anaesthetic used with other anaesthetic medicines, to produce and/or maintain heavy sleep during your operation. If you are a cardiac patient, it may also be used to help relieve any pain immediately following your operation.

Remifentanil may also be used for patients in the Intensive Care Unit to maintain sedation and relieve pain.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

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.

As with other opioids, remifentanil can be addictive. This is unlikely to happen when remifentanil is only used during your operation.

Use in children

This medicine should not be used in children less than 1 year old.

Before you are given this medicine

When you must not receive it

Do not receive this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, remifentanil or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

Before you receive it

Before you start to receive this medicine, you must tell your doctor if:

1. You have had any adverse reactions during an operation.
2. You have had any type of allergic reaction to opioid medicines (e.g. morphine, fentanyl, pethidine, codeine) or to any medicines used during an operation. You probably have an increased chance of being allergic to remifentanil if you are allergic to other opioids.
3. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
4. You have or have had any medical conditions, especially the following:

- slow heart beat
 - low blood pressure
 - chest or breathing problems.
5. You are currently pregnant or you plan to become pregnant.
Like most medicines, remifentanil is not recommended in pregnancy.
 4. You are currently breastfeeding or you plan to breast-feed.
Like most medicines, remifentanil is not recommended when breastfeeding. However, your doctor will discuss the possible risks and benefits of being given this medicine if you are breastfeeding.
 5. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.
Some medicines may interact with remifentanil. Tell your doctor if you have recently been taking medicines for blood pressure or heart problems (known as beta-blockers or calcium channel blockers).
Some medicines, such as benzodiazepines, may interfere with remifentanil. Your doctor or pharmacist will be able to tell you what to do when being given remifentanil with other medicines.

How this medicine is given

This medicine can be given into a vein in two ways:

- as a slow injection, or
- as a slow infusion.

This medicine will be administered by an anaesthetist or other highly trained doctor. You will never be expected to give yourself this medication. The dosage will vary according to many factors such as your body weight and the type of operation you have.

While you are using this medicine

Things to be careful of

If you are discharged early, following treatment with this medicine or any other anaesthetic agents, do not drive or operate machinery.

Possible side effects

Tell your doctor as soon as possible if you do not feel well after you have been given remifentanil, even if you do not think the problems are connected with this medicine or are not listed in this leaflet.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

- slow breathing
- breathlessness
- slow heart beat
- drop in blood pressure
- increased blood pressure which may cause a headache or sensation of warmth/flushing.
- muscle stiffness
- shivering
- nausea
- vomiting
- aches

Other side effects not listed above may occur in some patients.

Ask your doctor or pharmacist if you don't understand anything in this list.

Product description

What Remifentanil APOTEX looks like

1 mg, 2 mg and 5 mg powder for injection: white to off-white powder.

* Not all strengths may be available.

Ingredients

Each vial contains 1mg, 2 mg or 5 mg remifentanil (as hydrochloride) as the active ingredient.

It also contains the following inactive ingredients:

- glycine
- hydrochloric acid.

The powder is dissolved in a suitable sterile liquid before use.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

Remifentanil APOTEX:
1 mg (vial) AUST R 234710;
2 mg (vial) AUST R 234707;
5 mg (vial) AUST R 234702.

Sponsor

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