

Remifentanil Sandoz®

remifentanil [as hydrochloride] powder for injection

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Remifentanil Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

WHAT REMIFENTANIL SANDOZ IS USED FOR

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

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

It contains the active ingredient remifentanil. 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.

Ask your doctor or anaesthetist if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

As with other opioids, this medicine can be addictive. This is unlikely to happen when Remifentanil Sandoz is used during your operation.

BEFORE YOU ARE GIVEN REMIFENTANIL SANDOZ

When you must not be given Remifentanil Sandoz

Do not use this medicine if you have an allergy to:

- remifentanil or to any of the other ingredients listed at the end of this leaflet under Product Description.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Before you are given Remifentanil Sandoz

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- slow heart beat
- low blood pressure
- chest or breathing problems.

Tell your doctor if:

- you have had any adverse reactions during an operation
- you 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 this medicine if you are allergic to other opioids.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given Remifentanil Sandoz.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Remifentanil Sandoz may interfere with each other. These include:

- beta-blocker medicines used to treat high blood pressure
- calcium channel blocker medicines used to treat heart problems
- benzodiazepines used to treat sleeplessness and/or anxiety.

Your doctor and pharmacist have more information on medicines to be careful with or avoid before you are given this medicine.

HOW REMIFENTANIL SANDOZ IS GIVEN

Remifentanil Sandoz will be given into a vein by either as a slow injection or as a slow infusion.

It will be administered by an anaesthetist or another highly trained doctor. The doctor or anaesthetist will decide the amount of Remifentanil Sandoz to give to you according to your body weight and the type of operation you will have.

You will not be required to give this medication to yourself.

WHILE YOU ARE USING REMIFENTANIL SANDOZ

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.

SIDE EFFECTS

Tell your doctor, anaesthetist, pharmacist or nurse as soon as possible if you do not feel well after you have been given Remifentanil Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor, anaesthetist, pharmacist or nurse if you notice any of the following and they worry you:

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

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER USING REMIFENTANIL SANDOZ

Storage

Keep the medicine in the original container.

If you take it out of its original container it may not keep well.

Keep the medicine in a cool dry place where the temperature stays below 25°C.

PRODUCT DESCRIPTION

What it looks like

Remifentanil Sandoz comes in 3 strengths:

- Remifentanil Sandoz 1mg - 4mL clear glass vial with a latex-free rubber stopper, containing a white to almost white powder.
- Remifentanil Sandoz 2mg - 4mL clear glass vial with a latex-free rubber stopper, containing a white to almost white powder.
- Remifentanil Sandoz 5mg -10mL clear glass vial with a latex-free rubber stopper, containing a white to almost white powder.

Available in packs of 5 vials.

Ingredients

Active ingredient:

- Remifentanil Sandoz 1mg - 1mg remifentanil (as hydrochloride)
- Remifentanil Sandoz 2mg - 2mg remifentanil (as hydrochloride)
- Remifentanil Sandoz 5mg - 5mg remifentanil (as hydrochloride).

Inactive ingredients:

- glycine
- hydrochloric acid.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
 ABN 60 075 449 553
 19 Harris St
 Pyrmont NSW 2009
 Tel: 1800 634 500

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Australian Register Numbers

1mg Powder for Injection: AUST R
195285

2mg Powder for Injection: AUST R
195287

5mg Powder for Injection: AUST R
195286