

REMIFENTANIL Alphapharm

contains the active ingredient remifentanil (as hydrochloride)

Consumer Medicine Information

What is in this leaflet

This leaflet contains answers to some common questions about REMIFENTANIL Alphapharm.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking REMIFENTANIL Alphapharm against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What REMIFENTANIL Alphapharm is used for

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

REMIFENTANIL Alphapharm 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.

Your doctor may have prescribed REMIFENTANIL Alphapharm for another reason.

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

Ask your doctor if you have any questions about why REMIFENTANIL Alphapharm has been prescribed for you.

Before you are given REMIFENTANIL Alphapharm

When you must not receive it

Do not take REMIFENTANIL Alphapharm if you have an allergy to:

- any medicine containing remifentanil
- any of the ingredients listed at the end of this leaflet
- any other similar medicines

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.

Before you receive REMIFENTANIL Alphapharm

You must tell your doctor if:

- **you have had any adverse reactions during an operation**
- **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 Alphapharm if you are allergic to other opioids.**
- **you are allergic to any other medicines, foods, dyes or preservatives**
- **you have or have ever had any of the following medical conditions:**
 - slow heart beat
 - low blood pressure
 - chest or breathing problems.
- **you are pregnant, intend to become pregnant or are breastfeeding. Like most medicines, REMIFENTANIL Alphapharm is not recommended in pregnancy and breast-feeding. However, your doctor will discuss the possible risks and benefits of being given REMIFENTANIL Alphapharm if you are pregnant or breast-feeding.**

If you have not told your doctor about any of the above, tell them before you are given REMIFENTANIL Alphapharm.

Taking other medicines

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

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 Alphapharm. Your doctor or pharmacist will be able to tell you what to do when being given REMIFENTANIL Alphapharm with other medicines.

How REMIFENTANIL Alphapharm is given

REMIFENTANIL Alphapharm can be given into a vein in two ways:

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

REMIFENTANIL Alphapharm 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 REMIFENTANIL Alphapharm

Things to be careful of

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

Side effects

All medicines have unwanted side effects. Sometimes they are serious, most of the time they are not. In cases of serious side effects, you may need prompt medical attention.

REMIFENTANIL Alphapharm can cause the following commonly reported side-effects:

- 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

Do not be alarmed by this list of possible side effects. You may not experience any of them. If you need to know more about the drug, please consult your doctor. Also please be sure to tell your doctor of any unusual effects or symptoms.

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

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Product description

What it looks like

REMIFENTANIL Alphapharm is supplied as 1 mg, 2 mg or 5 mg of white to off-white powder in a glass vial.

Ingredients

Active Ingredients:

- REMIFENTANIL Alphapharm 1 mg

- REMIFENTANIL Alphapharm 2 mg
- REMIFENTANIL Alphapharm 5 mg

Inactive ingredients:

- glycine
- small amounts of hydrochloric acid to adjust the acidity of the solution.

REMIFENTANIL Alphapharm does not contain gluten or lactose.

Supplier

Alphapharm Pty Limited
(ABN 93 002 359 739)
Level 1, 30 The Bond
30 - 34 Hickson Road
Millers Point NSW 2000
Phone: (02) 9298 3999
www.alphapharm.com.au

Australian registration numbers:

- REMIFENTANIL Alphapharm 1 mg - AUST R 163901
- REMIFENTANIL Alphapharm 2 mg - AUST R 163902
- REMIFENTANIL Alphapharm 5 mg - AUST R 163903

This leaflet was prepared on 31 May 2013.