

# REMIFENTANIL ALPHAPHARM

*contains the active ingredient remifentanil (as hydrochloride)*

## CONSUMER MEDICINE INFORMATION

### WARNING

#### Limitations of use

REMIFENTANIL ALPHAPHARM should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

#### Hazardous and harmful use

REMIFENTANIL ALPHAPHARM poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

#### Life threatening respiratory depression

REMIFENTANIL ALPHAPHARM can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing), even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting REMIFENTANIL ALPHAPHARM and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

#### Use of other medicines while using REMIFENTANIL ALPHAPHARM

Using REMIFENTANIL ALPHAPHARM with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using REMIFENTANIL ALPHAPHARM.

### 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.

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

### **Addiction**

You can become addicted to REMIFENTANIL ALPHAPHARM even if you receive it exactly as prescribed. REMIFENTANIL ALPHAPHARM may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

### **Dependence**

As with all other opioid containing products, your body may become used to you using REMIFENTANIL ALPHAPHARM. Using it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop receiving REMIFENTANIL ALPHAPHARM suddenly.

### **Tolerance**

Tolerance to REMIFENTANIL ALPHAPHARM may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

### **Withdrawal**

If you stop receiving this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps

- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

REMIFENTANIL ALPHAPHARM given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

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## **Before you are given REMIFENTANIL ALPHAPHARM**

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### ***When you must not receive it***

**Do not use REMIFENTANIL ALPHAPHARM if you have an allergy to:**

- any medicine containing remifentanyl
- any of the ingredients listed at the end of this leaflet
- other pain-relieving medicines which are similar to fentanyl and which are related to the class of medicines known as opioids

Symptoms of an allergic reaction may be mild or severe. They 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, are breastfeeding or plan to breast feed. 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, other pain relievers, antihistamines antidepressants and alcohol, 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.

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## How REMIFENTANIL ALPHAPHARM is given

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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.

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## While you are using REMIFENTANIL ALPHAPHARM

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### *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.

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## Side effects

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**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.**

**Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.**

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.

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## Product description

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### *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*

Each vial contains 1 mg, 2 mg or 5 mg of remifentanil (as hydrochloride).

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 Ltd

Level 1, 30 The Bond  
30 - 34 Hickson Road  
Millers Point NSW 2000  
www.mylan.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

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