

# Consumer Medicine Information

## **RAPIFEN<sup>®</sup>**

**alfentanil hydrochloride**

0.5 mg/mL injection

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### **What is in this leaflet**

This leaflet answers some of the common questions about RAPIFEN<sup>®</sup> injection. It does not contain all of the available information. It does not take the place of talking to your doctor, pharmacist or anaesthetist.

If you have any concerns about using RAPIFEN<sup>®</sup>, ask your doctor, pharmacist or anaesthetist. Your doctor, pharmacist or anaesthetist has more information.

Keep this leaflet after your treatment has finished. You may need to read it again.

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### **What RAPIFEN<sup>®</sup> is used for**

RAPIFEN<sup>®</sup> is used to produce loss of feeling and consciousness in surgical procedures, and to prevent pain and discomfort during surgery.

RAPIFEN<sup>®</sup> belongs to the group of strong painkillers called opioid analgesics. These medicines relieve pain by blocking the nerves in the brain that recognise pain messages from the body.

Your doctor may have prescribed RAPIFEN<sup>®</sup> for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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### **Before you are given RAPIFEN<sup>®</sup>**

#### ***When you must not be given it***

Do not use RAPIFEN<sup>®</sup> if you know you are allergic to any of the ingredients. (See the last section of this leaflet for a list of ingredients). Signs of allergy include a skin rash, itching, shortness of breath and/or a swollen face.

Do not use RAPIFEN<sup>®</sup> if you know you cannot tolerate opioid painkillers, for example, morphine and pethidine.

Do not use RAPIFEN<sup>®</sup> if the packaging is torn or shows signs of tampering. Do not use RAPIFEN<sup>®</sup> beyond the expiry date (month and year) printed on the pack.

#### ***Before you are given it***

Certain people must use RAPIFEN<sup>®</sup> with caution. Ask your doctor for advice.

#### **Driving and Operating Machinery**

RAPIFEN<sup>®</sup> can affect your alertness and ability to drive and operate machinery. It is therefore advisable to wait up to 24 hours after RAPIFEN<sup>®</sup> has been given before performing these tasks. However, you should first ask your doctor or pharmacist for advice.

#### **You must tell your doctor if:**

- you are pregnant or planning to become pregnant
- you are breast-feeding or wish to breastfeed

- you have or have ever had liver or kidney problems
- you have heart problems
- you have a history of fits or have ever had a head injury or brain tumour
- you have problems with your breathing such as severe asthma, severe bronchitis or emphysema
- you have a thyroid gland that is underactive
- you drink alcohol on a regular basis

If you have not told your doctor or pharmacist about any of the above, tell them before you are given RAPIFEN<sup>®</sup>.

Your doctor will decide whether or not to treat you with RAPIFEN<sup>®</sup> or whether to adjust the dose or adapt your treatment.

### **Other medicines and alcohol**

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy from a pharmacy, supermarket or health food shop.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- medicines which make you feel drowsy or cause you to be slow to react, such as sleeping tablets, tranquillisers or strong pain-killers
- certain medicines used to treat heart disease such as diltiazem
- medicines used as antidepressants. In particular, antidepressants belonging to a group called monoamine oxidase inhibitors (MAOIs), which should be stopped for 2 weeks before RAPIFEN<sup>®</sup> is used.
- certain medicines used to treat mental disorders
- macrolide antibiotics such as erythromycin
- certain medicines used to treat HIV, such as ritonavir
- azole antifungals such as fluconazole, ketoconazole or itraconazole
- a medicine for the stomach called cimetidine
- an antiviral called ritonavir
- alcohol

RAPIFEN<sup>®</sup> can speed up and increase the sedative effects of alcohol and sleeping tablets. Be careful and tell your doctor if you are taking any of these products with RAPIFEN<sup>®</sup>.

There may also be some other medicines that may cause problems if used together with RAPIFEN<sup>®</sup>. So, make a point of telling your doctor or pharmacist which medicines you are using at the moment, and before you start taking any new medicines. They will tell you which medicines should not be used or what other measures (for example, a change of dose) are necessary.

## **Using RAPIFEN<sup>®</sup>**

### ***How it is given***

RAPIFEN<sup>®</sup> is injected into a vein (intravenous use). Your doctor will determine how much RAPIFEN<sup>®</sup> you need on the basis of your weight, age and medical condition.

### **Adults**

The usual dose of RAPIFEN<sup>®</sup> ranges from 7 micrograms per kilogram to 150 micrograms per kilogram depending on what it is being used for. Repeated doses may be given in some cases. If you are elderly, you may be given a lower dose of RAPIFEN<sup>®</sup>.

### **Children 1 to 12 years**

The usual dose of RAPIFEN<sup>®</sup> for children is the same as that used in adults. However, in some cases a higher dose or more frequent dosing may be required, as RAPIFEN<sup>®</sup> has a shorter duration of action in children.

**RAPIFEN<sup>®</sup> is not recommended for use in children younger than 1 year, as the safety of RAPIFEN<sup>®</sup> in this age group is not known.**

### ***If you are given too much (overdose)***

In the unlikely event that an overdose has been given, your doctor or anaesthetist will take the necessary actions. The main symptom is markedly weakened breathing. There are specific agents that can reverse the effects from an overdose of RAPIFEN<sup>®</sup>.

**Tell your doctor immediately if you experience any breathing difficulties.**

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## **Side Effects**

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All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

**Tell your doctor if you experience any of the following:**

- dizziness, nausea and vomiting
- low blood pressure which may cause headache, weakness or dizziness
- high blood pressure
- chills, tiredness, fever
- headache
- pain at injection site
- shivering
- agitation, crying, disorientation
- feeling of extreme happiness
- nosebleed, cough, excess carbon dioxide in blood
- hiccups
- itching
- sweating

**Tell your doctor immediately if you notice any of the following as you may need urgent medical care:**

- abnormally slow and/or weak breathing or temporary cessation of breathing
- cardiac or respiratory arrest
- sleepiness, sedation, unresponsiveness to stimuli, loss of consciousness, convulsion.
- muscle stiffness or involuntary muscle movements, including slow, stiff or jerking movements
- slow, fast or irregular heart beat
- blurred or double vision, visual disturbance, small pupils
- a feeling of choking which is caused by the spasm of the muscles around the voice box
- allergic reactions such as skin rash, shortness of breath, or swelling of the face, neck and throat
- allergic dermatitis, itching, redness of the skin.

You will be closely monitored for side effects during and after a RAPIFEN<sup>®</sup> injection.

Other complications relating to your procedure such as postoperative agitation or confusion; airway or neurological complications of anaesthesia or endotracheal intubation complication may also occur. You may also experience pain, including injection site, vein or procedural pain.

Other side effects not listed above may also occur in some people. Do not hesitate to report any other side effects to your doctor or pharmacist.

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## Product Description

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### *What it looks like*

RAPIFEN<sup>®</sup> is a clear, colourless solution contained in 2 mL glass ampoules. A carton of RAPIFEN<sup>®</sup> contains 5 ampoules.

### *Ingredients*

The 2 mL ampoule contains 1 mg of alfentanil, together with sodium chloride and water.

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## Sponsor

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