

RAPIFEN(R)

Alfentanil Hydrochloride Injection (equivalent to 0.5 mg/mL alfentanil)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about Rapifen. It does not contain all the information that is known about Rapifen.

It does not take the place of talking to your doctor, anaesthetist or pharmacist.

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

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

Keep this leaflet. You may need to read it again.

What RAPIFEN is for

Rapifen is a drug used to relieve pain and produce anaesthesia.

It can be used as a premedication before an operation, or with a general anaesthetic during an operation.

Rapifen belongs to a group of medicines called opioid (narcotic) analgesics.

Rapifen works by changing the messages that are sent to the brain about pain.

Your doctor will have explained why you are being treated with Rapifen and told you what dose you will be given.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Rapifen can be addictive, but when it is used only to relieve or prevent pain it is unlikely to become habit forming.

Before you are given RAPIFEN

When you must not use it

Rapifen should not be used for pain relief after surgery has taken place.

Rapifen is not generally given to children under 12 years.

You should not be given Rapifen if you are pregnant or breastfeeding unless your doctor says it is safe. Ask your doctor about the risks and benefits involved.

We do not know if it is safe for you to be given Rapifen while you are pregnant.

It may affect your baby if it is given early in pregnancy or in the last weeks before your baby is due.

Breast-feeding is not advisable for 24 hours after Rapifen has been given.

Rapifen injection will only be used if the solution is clear, the package is undamaged and the use by (expiry) date marked on the pack has not been passed.

Before you are given it

You must tell your doctor if:

1. you have been given Rapifen before and had any problems with it

2. you have any allergies to

- * any ingredients listed at the end of this leaflet
- * other opioid analgesics (pain killers) eg. morphine or pethidine.
- * any other substances

If you have an allergic reaction, you may get a skin rash, hay fever or an asthma attack.

3. you have any of these medical conditions

- * problems with your breathing such as severe asthma, severe bronchitis or emphysema
- * a history of fits or head injury
- * under-active thyroid
- * myasthenia gravis (muscle weakness)
- * heart problems
- * liver or kidney problems
- * excessive weight

It may not be safe for you to be given Rapifen or you may be given a reduced dose if you have any of these conditions.

Taking other medicines

Rapifen can increase the effects of alcohol. Tell your doctor about your consumption of alcohol and follow the doctor's advice.

Rapifen should not be used if you are taking selegiline (Eldepryl(TM)), a medicine for Parkinson's Disease.

Rapifen should not be used if you have taken within the last 14 days, a medicine used for depression (a MAO or monoamine oxidase inhibitor).

Examples of these are:

- * phenelzine(Nardil(TM))
- * tranylcypromide(Parnate(TM))

Tell your doctor if you are taking a medicine that makes you feel drowsy, such as sleeping tablets or strong pain killers.

Also tell your doctor if you are taking certain medicines for mental disorders. These include:-

- * chlorpromazine (Largactil(TM))
- * thioridazine (Melleril(TM))
- * haloperidol (Serenace(TM))

Also tell your doctor if you are taking:

- * an antibiotic called erythromycin
- * an antifungal called fluconazole, ketoconazole or itraconazole
- * a medicine for the stomach called cimetidine (Tagamet(TM))
- * an antiviral called ritonavir (Norvir(TM))
- * a heart medicine called diltiazem (Cardizem(TM))

If you are taking any of these drugs, you may be given a smaller dose of Rapifen, and also will be watched very closely.

Tell your doctor if you are taking any other medicines in addition to the ones above, including medicines that you buy without a prescription at the chemist, supermarket or health food shop.

These medicines may affect the way Rapifen works.

Your doctor or pharmacist can tell you what to do if you are taking any other medicines.

If you have not told your doctor about any of these things, tell them before you are given any Rapifen.

How RAPIFEN is given

Rapifen will be given to you by injection by specially trained anaesthetists.

The injection is given into a vein

Your Doctor will decide how much Rapifen you will need

Elderly people may be given a smaller dose

Overdose

The doctor or nurse giving you Rapifen will be experienced in its use, so it is extremely unlikely that you will be given too much.

In the unlikely event that an overdose has been given, your doctor or the anaesthetist will take the necessary actions. The symptoms of overdose could include:

- * breathing difficulties
- * muscle stiffness
- * lowering of blood pressure
- * lowering of heart rate

Rapifen doses should be carefully worked out, so problems with overdosage are unlikely. There are drugs, eg. naloxone or nalorphine, which can be used if needed to reverse the effects of too much Rapifen.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well after you have been given Rapifen.

Rapifen helps most people suffering severe pain, but it may have unwanted side-effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

After you have been given Rapifen you will probably feel light-headed, dizzy, sleepy and you may feel quite strange, especially if you are not lying down.

Tell your doctor or nurse if you notice any of the following side effects and they worry you.

Rapifen may cause

- * breathing difficulties
- * muscle stiffness
- * slowed heart beat
- * nausea and vomiting

Rapifen can cause breathing difficulties, which can last longer than its pain-killing effect.

Rapifen sometimes causes

- * low blood pressure
- * dizziness
- * spasm of the larynx (voice box)
- * rash
- * blurred vision
- * missed or irregular heart beats

Some people may get other side effects after being given Rapifen.

Rapifen may affect your alertness and ability to drive. Therefore you should not drive or operate machinery until your doctor advised that you can.

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

Storage

Rapifen should be kept in a cool dry place, protected from light, where the temperature stays below 25 degrees C.

Rapifen will be kept in a locked cupboard in the hospital pharmacy or operating theatre.

Rapifen should not be used after the date (month and year) printed after "EXP". The anaesthetist will inspect Rapifen before use to determine that it is still within its use by date.

Disposal

The hospital staff looking after you will dispose of any remaining Rapifen appropriately.

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Product description

Rapifen injection is a clear, colourless solution.

Ingredients

The active ingredient in Rapifen is alfentanil.

Rapifen contains 0.5 mg/mL of alfentanil, as the active ingredient

plus

Sodium chloride

Water for Injection BP

Rapifen is available in two size glass ampoules: a 2 mL and a 10 mL ampoule.

A carton of Rapifen contains 5 ampoules.

5 x 2 mL and 5 x 10mL

The 2 mL ampoule contains 1 mg of alfentanil.

The 10 mL ampoule contains 5 mg of alfentanil.

Supplier

Rapifen is sold in Australia by:

AstraZeneca Pty Ltd

ACN 009 682 311

Alma Road

NORTH RYDE NSW 2113

Tel: 1-800-805-342

This leaflet was prepared in December 2001.

Australian Registration Numbers:

1mg/2 mL ampoule AUSTR 50506

5 mg/10 mL ampoule AUSTR 50508