RAPIFEN®

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 analgesics.

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

Your doctor will have explained why you are being given RAPIFEN.

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 should not be used if you have an allergy, intolerance or hypersensitivity to:

- alfentanil

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

Symptoms of an allergic or hypersensitivity reaction may include:

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

RAPIFEN is not generally given to children under 12 years of age.

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 passed.

Before you are given it

You must tell your doctor if you:

- are pregnant or planning to become pregnant. Your doctor will decide if you can take RAPIFEN. It may affect your baby if it is given early in pregnancy or in the last weeks before your baby is due.

- are breastfeeding or wish to breastfeed. RAPIFEN may be excreted in breast milk. Breast-feeding is not advisable for 24 hours after RAPIFEN has been given.

Tell your doctor if you have any of the following 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
- are overweight or obese

Tell your doctor if you take any medicine that slows down your reactions (CNS depressants), especially benzodiazepines or related drugs or have problems with alcohol.

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.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food store.

Tell your doctor immediately and do not take RAPIFEN if you are taking:

- medicines for depression called Monoamine Oxidase (MAO) Inhibitors. These medicines must not be taken in the 14 days before RAPIFEN is given.

Also tell your doctor if you are taking:

- any anaesthetic agents such as propofol
- any medicine that slows down your reactions (CNS depressants) such as benzodiazepines or related drugs, sleeping pills, tranquillizers, medicines for mental disorders, alcohol, some illegal drugs.

  If you receive a strong pain killer or other CNS depressant after receiving RAPIFEN during surgery, the dose of the painkiller or other CNS depressants may need to be lowered to reduce the risk of potentially serious side effects such as breathing difficulties, with slow or shallow breathing, severe drowsiness and decreased awareness, coma and death.
- an antibiotic called erythromycin

- an antifungal called fluconazole, voriconazole, ketoconazole or itraconazole
- a medicine for the stomach called cimetidine
- an antiviral called ritonavir
- a heart medicine called diltiazem
- medicines for depression known as selective serotonin re-uptake inhibitors (SSRIs) or serotonin norepinephrine re-uptake inhibitors (SNRIs)

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

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

These medicines may be affected by RAPIFEN or may affect how well RAPIFEN works. Your doctor can tell you what to do if you are taking any of these medicines.

How RAPIFEN is given

RAPIFEN will be given to you by injection by a specially trained anaesthetist.

The injection is given into the vein (intravenous use).

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 occurs, 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

If these symptoms occur, you may be administered another medicine (e.g. naloxone) to help reverse the effects.

If you think you or anybody else has been given too much RAPIFEN, contact your doctor or nurse immediately.

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:

- nausea and vomiting
- dizziness
- drowsiness or sleepiness
- injection site pain or pain during the procedure

Tell your doctor or nurse as soon as possible if you have any of the following as you may need medical attention:

- feeling of extreme happiness (euphoric mood)
- visual disturbance such as blurred vision
- chills
- rash

Tell your doctor or nurse immediately if you experience:

- breathing difficulties, which can last longer than its pain-killing effect.
- slow, fast or irregular heartbeat.
- tightening of the chest or heart attack
- low or high blood pressure
- muscle stiffness or involuntary muscle movements, including slow, stiff or jerking movements
- spasm of the larynx (voice box)

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

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

Tell your doctor or nurse 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.

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

RAPIFEN also contains sodium chloride and water for injection.

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.

Sponsor

JANSSEN-CILAG Pty Ltd

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Tel: 1800 226 334

Australian Registration Numbers:

1mg/2 mL ampoule AUSTR 50506

5 mg/10 mL ampoule AUSTR 50508

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