RAPIFEN®

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

Consumer Medicine Information

WARNING
Limitations of use
RAPIFEN 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
RAPIFEN 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
RAPIFEN 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 RAPIFEN 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 RAPIFEN
Using RAPIFEN 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 RAPIFEN.

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.
- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

This medicine contains alfentanil which is an opioid medicine. Repeated use of opioid painkillers may result in the drug being less effective (you become accustomed to it). It may also lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on RAPIFEN, it is important that you consult your doctor.

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. The concomitant use of opioids and drugs used to treat epilepsy, nerve pain or anxiety (gabapentin and pregabalin) increases the risk of opioid overdose, respiratory depression and may be life-threatening.
- 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.

Addiction

You can become addicted to RAPIFEN even if you take it exactly as prescribed. RAPIFEN 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 taking RAPIFEN. Taking it may result in physical

dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking RAPIFEN suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to RAPIFEN 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

Continue taking your medicine for as long as your doctor tells you. If you stop having 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.

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

Also, if women receive this drug during pregnancy, there is a risk that their newborn infants will experience neonatal withdrawal syndrome.

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:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits
- 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 or phone the Poisons Information Centre (by calling 13 11 26).

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.

Do not use this medicine after the expiry date.

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 10 mL

The 2 mL ampoule contains 1 mg of alfentanil.

The 10 mL ampoule contains 5 mg of alfentanil.

Sponsor

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Australian Registration Numbers:

1 mg/2 mL ampoule AUSTR 50506

5 mg/10 mL ampoule AUSTR 50508

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