

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Rapifen[®] 500 micrograms/ml solution for injection or infusion

Alfentanil

Rapifen is a registered trademark

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or nurse
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1 What Rapifen is and what it is used for
- 2 What you need to know before you take Rapifen
- 3 How to take Rapifen
- 4 Possible side effects
- 5 How Rapifen is stored
- 6 Contents of the pack and other information

1 What Rapifen is and what it is used for

Rapifen contains a medicine called alfentanil hydrochloride. It belongs to a group of medicines called 'opioid analgesics'. Rapifen is a strong painkiller that works for a short period of time.

Rapifen is used to prevent or relieve pain during different types of surgery in adults and children of all ages, including babies.

In adults it can be:

- Used alone for short operations, when you go home on the same day
- Used with other medicines (anaesthetics) to put you to sleep for longer operations, when you may stay in hospital for a number of days
- Used if you are in intensive care and are having your breathing helped by a machine called a ventilator.

In children of all ages, including babies it can be:

- Used with other medicines (sedatives) for short operations, when you go home on the same day
- Used with other medicines (general anaesthetics) to put you to sleep for longer operations, when you may stay in hospital for a number of days

2 What you need to know before you take Rapifen

Do not take Rapifen if:

- You are allergic to alfentanil or any of the other ingredients of this medicine (listed in section 6)
- You are allergic to strong medicines for pain called ‘opioid analgesics’
- You suffer from breathing difficulties called ‘obstructive airway disease’ or ‘respiratory depression’. You may only be able to have Rapifen if your breathing is helped by a machine called a ventilator
- You are in labour or before the cord is clamped during a Caesarean section. Rapifen may affect the baby’s breathing
- You are taking any of the antidepressant medicines, known as monoamine oxidase inhibitors (MAOIs) or have taken them during the last two weeks. Concurrent administration of Rapifen and these drugs is contraindicated.

Do not have this medicine if any of the above applies to you. If you are not sure, talk to your doctor or nurse before you are given Rapifen.

Warnings and precautions

Talk to your doctor or nurse before you receive or are given this medicine if:

- You have or have ever had problems with your lungs, liver or kidneys
- You have a recent head injury or problems with blood pressure in the brain
- You have an underactive thyroid gland
- 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.

Your doctor will carefully monitor the amount of Rapifen given to you. If you are not sure if any of the above applies to you, talk to your doctor or nurse before having Rapifen.

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.

Concomitant use of Rapifen and benzodiazepines (that can help to reduce anxiety and seizures, relax the muscles, and induce sleep) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. 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. However if your doctor does prescribe Rapifen together with benzodiazepines and related drugs the dosage and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all medicines you are taking, and follow your doctor’s dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of sign and symptoms stated above.

Contact your doctor when experiencing such symptoms.

Use (even at therapeutic doses) may lead to physical dependence, which may result in you suffering withdrawal effects and a recurrence of your problems if you suddenly stop taking this medicine treatment.

Please tell your doctor if you are pregnant, might become pregnant or are breast-feeding (see Pregnancy section for more information).

Tell your doctor or pharmacist if you have experienced increased sensitivity to pain despite the fact that you are taking increasing doses (hyperalgesia). Your doctor will decide whether you will need a change in dose or stop taking this medicine.

Special monitoring

- Rapifen may make you breathe more slowly. Your breathing will be carefully monitored until it returns to normal
- Your blood pressure and heart rate will also be monitored

Babies, children and adolescents

Rapifen can cause breathing difficulties, especially in babies and very young children. When babies and very young children are given Rapifen:

- Their breathing will be carefully monitored during the operation and for some time afterwards.
- The doctor may give a medicine to relax the muscles and to prevent them becoming stiff.

Other medicines and Rapifen

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

In particular, do not have this medicine and tell your doctor or nurse if you have taken:

- Medicines for depression called 'monoamine oxidase inhibitors' (MAOIs) in the past two weeks
- 'Selective Serotonin Reuptake Inhibitors' (SSRIs) or 'Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)'

If this applies to you, do **not** have Rapifen.

The effects of Rapifen or any of the following medicines may be increased when they are taken together:

- Cimetidine - for ulcers, stomach ache and heartburn
- Erythromycin - an antibiotic
- Diltiazem - for a heart problem
- Medicines to change the way you think, feel or behave
- Other strong painkillers, for example 'opioid analgesics'
- Medicines for high blood pressure or heart problems called 'beta- blockers'
- Medicines for anxiety or to help you sleep such as tranquillisers or sleeping pills
- Medicines that affect your central nervous system (CNS depressants) such as medicines for mental health disorders
- Medicines for fungal infections called fluconazole, voriconazole, ketoconazole or itraconazole

- Medicines for HIV infection (called antiviral protease inhibitors) such as ritonavir

Talk to your doctor before having Rapifen if you are taking any of these medicines. They may have to change the amount of Rapifen or the other medicines you are given.

The effects of Rapifen or the following medicines may also be changed when they are taken together, but your doctor will know about these:

- Medicines for putting you to sleep called 'anaesthetics'
- Medicines to relax muscles

Rapifen with alcohol

Tell your doctor or nurse if you use alcohol regularly, because the effect of Rapifen may be increased or last longer.

Pregnancy and breast-feeding

You must tell your doctor before having Rapifen if you are pregnant or think you may be pregnant.

Rapifen is not recommended during childbirth as it crosses the placenta and can affect your baby's breathing.

You may still be able to have Rapifen if your doctor thinks you need to.

Rapifen may get into breast milk. Do not breast-feed or use breast milk that has been expressed during 24 hours after having Rapifen.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

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

Driving and using machines

Do not drive or use any tools or machines for at least 24 hours after having Rapifen. You may be less alert than usual.

This medicine can affect your ability to drive. Do not drive whilst taking this medicine until you know how this medicine affects you. It may be an offence to drive if your ability to drive safely is affected. There is further information for patients who are intending to drive in Great Britain – go to <https://www.gov.uk/drug-driving-law>.

Rapifen contains sodium chloride

If you need to control your salt intake (controlled sodium diet) be aware that:

- The contents of the ampoule may be diluted in a salt solution before being given to you. This salt solution also contains sodium

For Rapifen 2 ml ampoule: This medicine contains less than 1 mmol sodium (23 mg) per 2 ml ampoule, that is to say essentially 'sodium-free'.

For Rapifen 10 ml ampoule: This medicine contains 35.4 mg sodium (main component of cooking/table salt) in each 10 ml ampoule. This is equivalent to 1.8 % of the recommended maximum daily dietary intake of sodium for an adult.

3 How to take Rapifen

Rapifen is given in hospital by a doctor experienced in using this type of medicine. Check with your doctor or nurse if you are not sure about anything.

How Rapifen is given

- Rapifen is given as a drip (infusion) or an injection into a vein
- You will probably be given an anaesthetic at the same time if you are having an operation

How much Rapifen is given

Your doctor will decide how much Rapifen you need. This may depend on:

- Your body weight
- Your general health
- Your age
- The type of operation you are having or if you are in Intensive Care

For operations

Adults:

Rapifen given by injection to start anaesthesia

- You will be given a slow injection of at least 120 micrograms per kilogram of body weight

For short operations where Rapifen given alone by injection

- You will usually be given an initial dose of 7 micrograms per kilogram up to 500 micrograms
- It will be given slowly, over about 30 seconds
- If necessary, you will be given further injections of 3.5 micrograms per kilogram of body weight or 250 micrograms during the operation

For longer operations when your breathing is helped by a machine (ventilator) and Rapifen given by injection

- The initial dose will be 30-50 micrograms per kilogram of body weight
- If necessary, further injections of 15 micrograms per kilogram of body weight will be given during the operation

Rapifen given as a drip (infusion)

- You will usually be given an initial dose of 50 to 100 micrograms per kilogram of body weight over 10 - 15 minutes
- If necessary, this may be followed by 0.5 to 1 micrograms per kilogram of body weight during each minute of your operation
- The drip will normally be stopped 10 - 20 minutes before the end of your operation

Babies, children and adolescents:

Rapifen is used with other medicines (anaesthetics or sedatives) in babies, children and adolescents.

- **In children**

When Rapifen is given by injection as an anaesthetic or to relieve pain

- You will usually be given an initial dose of 10 to 20 micrograms per kilogram of body weight
- If necessary, you will be given further injections of 5 to 10 micrograms per kilogram of body weight

When Rapifen is given as a drip (infusion) to maintain pain relief during surgery

- You will usually be given a dose of 0.5 to 2 micrograms per kilogram of body weight per minute
- If the Rapifen drip is combined with an anaesthetic, you will usually be given a dose of approximately 1 microgram per kilogram of body weight per minute

- **In newborn babies**, a lower dose of Rapifen may be given
- **Adolescents** will usually be given a similar dose to adults

For treatment in intensive care

Adults:

- The initial dose is usually 2 milligrams per hour or 30 micrograms per kilogram of body weight per hour
- If you need Rapifen over a long time, the usual dose is 0.4 to 0.5 micrograms per kilogram of body weight per minute
- Sometimes you might be given an extra dose of 0.5 – 1 milligrams by injection

Babies, children and adolescents:

- Rapifen is not recommended for children in intensive care

Elderly or ill patients

Less Rapifen may be used in patients that are elderly or weak due to ill health.

If you have been given too much Rapifen

It is unlikely that you will be given too much Rapifen. This will be monitored during your operation.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Your doctor will monitor these effects during your operation.

Tell your doctor or seek medical attention immediately if you have the following side effects:

- Serious allergic reaction which may cause difficulty in breathing, wheezing or coughing and hives or nettle rash (urticaria)

Other side effects include:

Very common (affects more than 1 in 10 people)

- Feeling sick (nausea) or being sick (vomiting)

Common (affects less than 1 in 10 people)

- Feeling excited or unusually carefree
- Breathing more slowly or weakly than usual or breathing may even stop. If necessary, your breathing will be helped by a machine (ventilator)
- Dizziness
- Feeling sleepy or tired
- Uncontrolled movements, muscle stiffness
- Problems with eyesight
- Slowing or speeding of heartbeat
- Low or high blood pressure
- Shivering or feeling cold
- Pain where the injection was given

Uncommon (affects less than 1 in 100 patients)

- Headache
- An irregular heartbeat
- Hiccups
- Choking caused by cramping (spasm) of the muscles in your throat
- Sweating or skin rash
- Agitation, confusion (after an operation)

Rare (affects less than 1 in 1,000 people)

- Feeling tearful or weepy
- Nose bleeds
- Wheezing, coughing
- Itchy skin

Frequency not known

- Feeling disoriented
- Unconsciousness (after an operation)
- Fits or twitching
- Shrinking of the pupils
- Fever
- Redness of the skin
- Cardiac arrest (when your heart stops)

Side effects in babies, children and adolescents

The frequency and type of side effects in children and adolescents are similar to those described above. Muscle twitching or stiffness may occur more commonly in newborn babies than in older people given Rapifen.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5 How Rapifen is stored

Keep out of the sight and reach of children. Rapifen is stored in a Controlled Drug Store in the hospital pharmacy. This medicinal product does not require any special storage conditions.

Rapifen will not be used after the expiry date stated on the carton and ampoule. The expiry date refers to the last day of that month.

6 Contents of the pack and other information

What Rapifen contains

- The active substance is alfentanil hydrochloride. Each millilitre (ml) contains 500 micrograms of alfentanil (as hydrochloride).
- The other ingredients are sodium chloride and water.

What Rapifen looks like and contents of the pack:

Rapifen 500 micrograms/ml solution for injection or infusion is supplied in a clear glass ampoule containing 2 ml (packs of 10) or 10 ml (packs of 5).

Marketing Authorisation Holder:

Piramal Critical Care B.V.,
Rouboslaan 32,
2252TR,
Voorschoten,
The Netherlands

Manufacturer:

Piramal Critical Care B.V.,
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For information in large print, tape, CD or Braille, telephone 1800 709 122.

This leaflet was last revised in August 2022.

The following information is intended for healthcare professionals only:

Rapifen ampoules are for single use only. Discard any unused contents.

When Rapifen is given, it may only be mixed with:

- Sodium chloride solution
- Dextrose solution
- Compound sodium lactate solution (Hartmann's solution) These mixtures must be used within 24 hours of preparation.

Wear gloves while opening ampoule. Accidental dermal exposure should be

treated by rinsing the affected area with water. Avoid use of soap, alcohol, and other cleaning materials that may cause chemical or physical abrasions to the skin.

Please refer to the Summary of Product Characteristics for further information on the use of this medicinal product.