

PACKAGE LEAFLET: INFORMATION FOR THE USER

Rapifen®

500 micrograms/ml solution for injection or infusion

Alfentanil hydrochloride

This medicine contains alfentanil hydrochloride, which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

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 use Rapifen
3. How to use Rapifen
4. Possible side effects
5. How to store Rapifen
6. Contents of the pack and other information

1. What Rapifen is and what it is used for

This medicine has been prescribed for you for pain relief. It contains alfentanil hydrochloride which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it and when it is appropriate to stop, and how to do it safely.

2. What you need to know before you use Rapifen

Do not have Rapifen if:

- You are allergic to alfentanil hydrochloride 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

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

Warnings and precautions

Talk to your prescriber before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Rapifen to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.
- 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 [product name], it is important that you consult your doctor.

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

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment. Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Talk to your doctor or nurse before being given this medicine also if you have ever had:

- Problems with your lungs, liver or kidneys
- Problems with alcohol (alcoholism)
- Long-term treatment with strong painkillers

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.

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

If this applies to you, do not have Rapifen.

It is especially important to talk to your doctor or nurse if you are taking any of the following:

- 'Selective Serotonin Reuptake Inhibitors' (SSRIs) or 'Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)'

The effects of Rapifen may last longer if you are taking:

- Cimetidine - for ulcers, stomach ache and heartburn
- Erythromycin - an antibiotic
- Diltiazem - for a heart problem

Talk to your doctor before having Rapifen if you are taking any of these medicines.

The effects of Rapifen or any of these medicines may be increased when they are taken together

- Other strong medicines for pain, for example 'opioid analgesics' such as morphine or codeine

- Medicines for high blood pressure or heart problems called ‘beta-blockers’
 - Medicines for putting you to sleep called ‘anaesthetic agents’
 - 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 disorders
 - Medicines for epilepsy such as clobazam, clonazepam or phenobarbital
- 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.

Certain medicines may affect the way Rapifen works

- Medicines for fungal infections called fluconazole, voriconazole, ketoconazole or itraconazole
- Medicines for HIV infection (called antiviral protease inhibitors) such as ritonavir, indinavir or saquinavir

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

Rapifen with alcohol

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

Rapifen with benzodiazepines

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.

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.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and

- You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
- It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Rapifen contains sodium chloride

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.

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

3. How to use Rapifen

Rapifen is given 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 may be given an anaesthetic at the same time

How much Rapifen is given

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

- Your body weight in kilograms
- Your general health
- Your age
- The type of operation you are having

Adults

Rapifen given as a drip (infusion)

- The dose of Rapifen is based on body weight in kilograms
- You will usually be given an initial dose of 50 to 100 micrograms per kilogram
- If necessary, this may be followed by 0.5 to 1 micrograms per kilogram during each minute of your operation
- The drip will normally be stopped 30 minutes before the end of your operation

Rapifen given by injection

If you are to breathe by yourself

- You will usually be given an initial dose of 500 micrograms
- It will be given slowly, over about 30 seconds

- If necessary, you will be given further injections of 250 micrograms during the operation

When your breathing is helped by a machine (ventilator)

- The dose of Rapifen is based on body weight in kilograms
- The initial dose will be 30-50 micrograms per kilogram
- If necessary, further injections of 15 micrograms per kilogram will be given during the operation
- The last injection will be given no later than 10 minutes before the end of the 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 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.

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.

Your prescriber should have discussed with you, how long the course of drip (infusion) will last.

They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

If you stop taking Rapifen

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do

this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

Pregnancy and breast-feeding

Do not take Rapifen if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Rapifen during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated. Do not take Rapifen while you are breastfeeding as alfentanil passes into breast milk and will affect your baby.

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.

Very common (affects more than 1 in 10 people)

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

Common (affects fewer than 1 in 10 people)

- Slower or weaker breathing or your breathing may stop for a short period of time. If necessary, your breathing will be helped by a machine (ventilator)
- Muscle twitching or stiffness, which may involve your chest muscles
- Dizziness and fainting. These are signs of lowered blood pressure
- Raised blood pressure
- Feeling tired or sleepy
- Feeling cold or shivering
- Feeling excited or unusually carefree
- Feeling calm and relaxed
- Fast or slow heartbeat
- Blurred or double vision
- Pain where the injection was given
- Unusual movements

Uncommon (affects fewer than 1 in 100 people):

- Choking caused by cramping (spasm) of the muscles in your throat
- Slower or weaker breathing returning
- Feeling sleepy or unresponsive
- Breathing faster possibly with flushing of the skin
- An irregular heartbeat
- Feeling agitated or disoriented
- Sweating or skin rash
- Headache
- Hiccups
- General body aches and pains

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

- Difficulty in breathing, wheezing or shortness of breath
- Nose bleeds
- Itchy skin
- Feeling agitated
- Crying

Other possible side effects:

- Serious allergic reaction which may cause difficulty in breathing, wheezing or coughing, and hives or nettle rash (urticaria)
- Breathing can stop completely, which may be fatal
- Heart attack
- Fits or seizures
- Loss of consciousness after your operation
- Pupils of the eye much smaller than normal
- Fever or high temperature
- Redness of the skin or rash
- Feeling disorientated
- Muscle twitches

Unknown frequency:

dependence and addiction (see section “How do I know if I am addicted?”).

Drug Withdrawal

When you stop taking Rapifen, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Rapifen, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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

5. How to store Rapifen

Rapifen is kept out of the reach and sight of children. It is stored in a Controlled Drug Store in the hospital pharmacy. This medicinal product does not require any special storage conditions. Rapifen ampoules are for single use only. Any unused contents should be discarded.

When Rapifen is given, it can be mixed with:

- Sodium chloride solution
- Dextrose solution
- Compound sodium lactate solution (Hartmann's solution)

These mixtures are used within 24 hours of preparation.

Rapifen will not be used after the expiry date stated on the label. 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 the hydrochloride).
- The other ingredients are sodium chloride and water.

What Rapifen looks like and contents of the pack

Rapifen is supplied in a clear glass ampoule containing 2 ml (packs of 10) or 10 ml (packs of 5 and 10) of liquid.

Marketing Authorisation Holder:

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