APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S6

ALTIREM IV 1 mg powder for solution for infusion/injection

ALTIREM IV 2 mg powder for solution for infusion/injection

ALTIREM IV 5 mg powder for solution for infusion/injection

Remifentanil hydrochloride equivalent to remifentanil

Sugar free. Preservative free.

Read all of this leaflet carefully before you start are given ALTIREM IV

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.

What is in this leaflet

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1. What ALTIREM IV is and what it is used for

ALTIREM IV contains the active substance remifentanil which belongs to a group of medicines called opioids. Remifentanil starts to work quickly, and its effect lasts for a very short time.

Remifentanil is a strong pain-relieving medicine used together with numbing medicines (anaesthetics):

- to help put you to sleep before an operation
- to keep you asleep and stop you feeling pain during an operation
- to make you feel sleepy and stop you feeling pain while you receive treatment in an Intensive Care Unit.

2. What you need to know before you are administered ALTIREM IV

ALTIREM IV should not be administered:

- if you are hypersensitive (allergic) to remifentanil or any of the other ingredients of this medicine (listed in section 6) or medicines in the same class (opioids)
- if you are hypersensitive (allergic) to any other pain-relieving medicines which are similar to fentanyl; and which are related to the class of medicines known as opioids, or to any of the ingredients of ALTIREM IV (see section 6)

  Opioids are used to treat acute pain. Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: Wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lump rash (“hives”) or fainting
- as injection into the spinal canal

- together with nitrous oxide and oxygen alone at altitudes above sea level
- without artificial ventilation
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Tell your doctor or healthcare professional before being given ALTIREM IV if:

- you are allergic (hypersensitive) to any other opioid medicines, such as morphine or codeine
- you are taking sedative medicines such as benzodiazepines, commonly used to treat anxiety, panic disorders, insomnia, epilepsy and alcohol dependence (see Other medicines and ALTIREM IV)
- suffer from serotonin syndrome

  if your doctor recognizes that you may develop serotonin syndrome (a potentially life threatening syndrome), the doctor will decide if the administration of ALTIREM IV has to be stopped. Signs of serotonin syndrome include high body temperature, high blood pressure, fast heartbeat, excess sweating, shivering, widening of your pupils, increased reflexes, muscle twitching, tremor, muscle rigidity, lack of coordination, gut-related cramps, feeling sick or coma
- you are undergoing surgery, your doctor will administer an alternative pain or sleeping medicine to manage any pain.

Take special care with ALTIREM IV and tell your doctor if:

- you have a personal or family history of substance abuse or mental health disorders (there is an increased risk of addiction)
- you are over 65 years of age, as you may experience the effects of ALTIREM IV for a longer time period
- you are dehydrated, have lost a lot of blood or have been feeling weak or unwell as you are more likely to experience effects on your heart (low blood pressure or a slower than normal heart rate)
- you have liver problems as ALTIREM IV may affect your ability to breathe
- you are overweight as your doctor might reduce the dosage of ALTIREM IV
- you have a neuromuscular disorder that causes weakness in the muscles your body uses for movement as you may experience more pronounced muscle tension, or stiffness that may affect your breathing
- you have a severe condition that affects parts of your body or even your whole body such as poorly controlled diabetes, poorly controlled high blood pressure, lung disorders, heart problems
- you have a severe condition that is life-threatening such as poorly controlled disorders or at end stage, heart conditions or kidney failure.

You should not make any legal decisions or sign any contracts for 24 hours after receiving ALTIREM IV, as this medicine may interfere with your daily activities.

If you are unsure if any of the above apply to you, talk to your doctor, pharmacist or nurse before you are given ALTIREM IV.

Children

ALTIREM IV should not be given to infants under 1 year of age as it is unlikely to be safe and there is limited information on the use of ALTIREM IV in this age group.

Other medicines and ALTIREM IV

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- sedatives or medicines called benzodiazepines (used to treat anxiety, panic attacks, insomnia, seizures and alcohol dependence) as these medicines increase 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. However, if your doctor does prescribe ALTIREM IV together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor
- medicines for your heart or blood pressure, such as beta blockers (these include atenolol, metoprolol, carvedilol, propranolol and bisoprolol) or calcium channel blockers (these include amlodipine, diltiazem and nifedipine) as you may experience effects on your heart (low blood pressure or a slower than normal heart rate)

- medicines for the treatment of depression such as selective serotonin reuptake inhibitors (SSRIs), serotonin noradrenaline reuptake inhibitors (SNRIs) and monoamine oxidase inhibitors (MAOIs). It is not recommended to use these medicines at the same time as this medicine as they may increase the risk of serotonin syndrome, a potentially life-threatening condition.

ALTIREM IV with alcohol

You should avoid alcohol for up to 24 hours after being given ALTIREM IV as you may experience increased side effects (sleepiness, difficulty breathing, coma and slow brain function).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before being given ALTIREM IV.

You should not be administered ALTIREM IV if you are pregnant or breastfeeding (see What you need to know before you are given ALTIREM IV).

Driving and using machines

ALTIREM IV has major influence on the ability to drive and use machines.

If you are only staying in hospital for the day, your doctor will tell you how long to wait before leaving the hospital or driving a car. It can be dangerous to drive too soon after having an operation. ALTIREM IV can affect your ability to drive as it may make you sleepy or dizzy. Do not drive after taking ALTIREM IV until you know how it affects you.

It is not always possible to predict to what extent ALTIREM IV may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ALTIREM IV affects them.

3. How to use ALTIREM IV

You will not be expected to administer ALTIREM IV to yourself. It will be administered to you by a person who is qualified to do so. Your doctor will decide the correct dose for you.

ALTIREM IV can be given:

- as a single injection into your vein
- as a continuous infusion into your vein. This is where ALTIREM IV is slowly given to you over a longer period of time.

The way you are given ALTIREM IV and the dose you receive will depend on:

- your weight
- the operation you have
- how much pain you will be in
- how sleepy the medical staff want you to be in the Intensive Care Unit.

The dose varies from one patient to another.

If you are administered more ALTIREM IV than you should

Since a healthcare professional will administer ALTIREM IV, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

The effects of ALTIREM IV are carefully monitored throughout your operation and in intensive care, and appropriate action will be taken promptly if you receive too much.

After your operation

Tell your doctor or nurse if you are in pain. If you are in pain after your procedure, they will be able to give you other painkillers.

4. Possible side effects

ALTIREM IV can have side effects.

Not all side effects reported for ALTIREM IV are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using ALTIREM IV, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, ALTIREM IV will be stopped immediately:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

- fainting

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ALTIREM IV. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

- muscle stiffness
- slow than normal heartbeat, or other heart problems
- breathing stops (apnoea)
- shallow breathing, problems breathing (hypoxia)
- physical need for ALTIREM IV (medicine dependency) or the need for increasing doses over time to get the same effect (medicine tolerance)
- seizures (fits), serotonin syndrome.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- high blood pressure
- low blood pressure (feeling dizzy or lightheaded)
- cough
- nausea, vomiting
- itching
- weight gain, abnormal liver test results.

Less frequent side effects:

- headache
- constipation
- liver problems, abnormal blood test results including increased cholesterol levels
- upper abdominal pain
- abdominal pain that radiates to your back
- tenderness when touching the abdomen
- fever
- rapid pulse
- nausea and vomiting.

Other side effects that you may experience when you wake up after having ALTIREM IV include:

Frequent side effects:

- shivering
- increases in blood pressure.

Less frequent side effects:

- feeling very calm or drowsy (sedation)
- continuous or prolonged pain
- restlessness (agitation).

The following side effects have been reported but the frequency for them to occur is not known:

- a type of irregular heartbeat (atrioventricular block)

- medicine dependency (physical need for ALTIREM IV) or medicine tolerance (the need for increasing doses over time to get the same effect)
- convulsions (fits)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of ALTIREM IV.

You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store ALTIREM IV

Store all medicines out of reach of children.

Store at or below 25 ºC.

Do not freeze. Keep the vial in the outer carton until required for use.

Reconstituted solution: Store at 25 ºC and use within 24 hours. Discard any unused solution.

When ALTIREM IV is made up it should be used straight away.

Do not use ALTIREM IV unless it is clear, colourless and practically free from particulate matter.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ALTIREM IV contains

The active substance is remifentanil hydrochloride equivalent to remifentanil.

The reconstituted solutions of ALTIREM IV contain 1 mg per ml of remifentanil as remifentanil hydrochloride.

ALTIREM IV 1 mg: Each single dose vial contains remifentanil hydrochloride equivalent to 1 mg remifentanil.

ALTIREM IV 2 mg: Each single dose vial contains remifentanil hydrochloride equivalent to 2 mg remifentanil.

ALTIREM IV 5 mg: Each single dose vial contains remifentanil hydrochloride equivalent to 5 mg remifentanil.

Sugar free. Preservative free.

The other ingredients are

Glycine and hydrochloric acid (for pH adjustment).

Reconstitution:

ALTIREM IV should be prepared for intravenous use by adding, as appropriate 1, 2, or 5 mL of diluent (refer below to the list of IV fluids) to give a reconstituted solution with a concentration of 1 mg/ml remifentanil. The reconstituted solution is clear, colourless, and practically free from particulate material. After reconstitution, visually inspect the product (where the container permits)

for particulate material, discolouration or damage of container. Discard any solution where such defects are observed. Reconstituted product is for single use only. Any unused material should be discarded.

The reconstituted solution is stable for 24 hours at room temperature (25 ºC) and further dilution to 20 to 250 µg/mL (50 µg/mL is the recommended dilution for adults and 20 - 25 µg/mL for paediatric patients aged 1 year and over) with one of the following IV fluids below:

- Sterilised Water for Injections
- 5 % Dextrose Injection
- 5 % Dextrose and 0,9 % Sodium Chloride Injection
- 0,9 % Sodium Chloride Injection
- 0,45 % Sodium Chloride Injection.

After dilution, visually inspect the product to ensure it is clear, colourless, practically free from particulate matter and the container is undamaged. Discard any solution where such defects are observed.

ALTIREM IV should not be reconstituted, diluted or mixed with Lactated Ringer's Injection or Lactated Ringer's and 5 % Dextrose Injection.

ALTIREM IV should not be mixed with propofol in the same infusion bag prior to administration.

ALTIREM IV should not be administered into the same intravenous line with blood/serum/plasma.

ALTIREM IV should not be mixed with other medicines before administration.

What ALTIREM IV looks like and contents of the pack

ALTIREM IV is a sterile, endotoxin free, preservative free, white to off white, lyophilised powder. The powder will be mixed with an appropriate fluid before being injected. When mixed to form a solution, ALTIREM IV is clear and colourless.

ALTIREM IV 1 mg is available in a clear, colourless glass (Type I), 3 mL vial, closed with a grey bromobutyl stopper and sealed with an aluminium cap having a light blue plastic flip-off cover. Five vials are placed in plastic cases and packed in carton boxes. Pack size of 5 and 10 vials.

ALTIREM IV 2 mg is available in a clear, colourless glass (Type I), 5 mL vial, closed with a grey bromobutyl stopper and sealed with an aluminium cap having a blue plastic flip-off cover. Five vials are placed in plastic cases and packed in carton boxes. Pack size of 5 and 10 vials.

ALTIREM IV 5 mg is available in a clear, colourless glass (Type I), 10 mL vial, closed with a grey bromobutyl stopper and sealed with an aluminium cap having a dark blue plastic flip-off cover. Five vials are placed in plastic cases and packed in carton boxes. Pack size of 5 and 10 vials. Not all pack sizes are necessarily marketed.

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