

ALTIMRE IV

SCHEDULING STATUS [56]

1. NAME OF THE MEDICINE

ALTIMRE IV 1 mg powder for solution for infusion/injection
ALTIMRE IV 2 mg powder for solution for infusion/injection
ALTIMRE IV 5 mg powder for solution for infusion/injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The reconstituted solutions of ALTIMRE IV contain 1 mg per mL of remifentanyl as remifentanyl hydrochloride.
ALTIMRE IV 1 mg: Each single dose vial contains remifentanyl hydrochloride equivalent to 1 mg remifentanyl.
ALTIMRE IV 2 mg: Each single dose vial contains remifentanyl hydrochloride equivalent to 2 mg remifentanyl.
ALTIMRE IV 5 mg: Each single dose vial contains remifentanyl hydrochloride equivalent to 5 mg remifentanyl.

Sugar free. Preservative free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for solution for infusion or injection.
ALTIMRE IV is a sterile, endotoxin-free, preservative free, white to off-white, lyophilised powder, to be reconstituted before intravenous (IV) administration.

After reconstitution, solutions of ALTIMRE IV are clear and colourless.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ALTIMRE IV is indicated for the provision of analgesia and as an aid to sedation (up to 72 hours sedation) in mechanically ventilated intensive care patients. Safety and efficacy beyond 72 hours have not been demonstrated.

4.2 Posology and method of administration

ALTIMRE IV should be administered only by persons specifically trained in the use of anaesthetic medicines and the recognition and management of the expected adverse effects of potent opioids, including respiratory and cardiac resuscitation such as the establishment and maintenance of a patent airway and assisted ventilation.

Posology

GENERAL ANAESTHESIA

The administration of ALTIMRE IV must be individualised based on the patient's response.

Adults

The following table summarises the starting infusion rates and dosages range:

Dosage guidelines for adults

Indication	Bolus infusion of ALTIMRE IV (µg/kg)	Continuous infusion of ALTIMRE IV (µg/kg/min)	Starting rate	Range
With induction of anaesthesia in ventilated patients	(given over not less than 30 seconds)	0.5 - 1.0	-	-
Maintenance of anaesthesia in ventilated patients				
Isosulfurane (starting dose 0.5 MAC (minimum alveolar concentration))	0.5 - 1.0	0.25	0.05 - 0.5	
Propofol (starting dose 1.0 µg/kg/min)	0.5 - 1.0	0.25	0.05 - 0.5	

At the doses recommended, ALTIMRE IV significantly reduced the amount of hypnotic medicine required to maintain anaesthesia. Therefore, isoflurane should be administered as recommended above to avoid excessive depth of anaesthesia (see section 4.5).

Induction of anaesthesia

ALTIMRE IV should be administered with a hypnotic medicine, such as isoflurane, for the induction of anaesthesia.
ALTIMRE IV should be administered at an infusion rate of 0.5 - 1.0 µg/kg/min with or without an initial bolus infusion of 1 µg/kg over not less than 30 seconds. If endotracheal intubation is to occur more than 8 - 10 minutes after the start of the ALTIMRE IV infusion, then a bolus infusion is not necessary.

Maintenance of anaesthesia

After endotracheal intubation, the infusion rate of ALTIMRE IV should be decreased, according to the anaesthetic technique, as indicated in the above table. Due to the fast onset and short duration of action of ALTIMRE IV, the rate of administration during anaesthesia can be titrated upward in 25 - 100 % increments or downward in 25 - 50 % decrements, every 2 - 5 minutes to obtain the desired level of μ -opioid receptor response. In response to light anaesthesia, supplemental bolus infusions may be administered every 2 - 5 minutes. The use of ALTIMRE IV to treat pain during the post-operative period is not recommended in patients who are breathing spontaneously.

Guidelines for discontinuation

Due to the very rapid offset of action of remifentanyl as in ALTIMRE IV, residual opioid activity will be reduced within 5 - 10 minutes after discontinuation. For those patients undergoing surgical procedures where post-operative pain is anticipated, analgesic should be administered prior to, or immediately following discontinuation of ALTIMRE IV. Sufficient time must be allowed to reach the maximum effect of the longer acting analgesic. The choice of analgesic should be appropriate for the patient's surgical procedure and the level of post-operative care.

Concomitant medication

ALTIMRE IV decreases the amounts or doses of inhaled anaesthetics, hypnotics and benzodiazepines required for anaesthesia (see section 4.5).

Paediatric patients (1 - 12 years of age)

Induction of anaesthesia
ALTIMRE IV is not recommended for the induction of anaesthesia, as insufficient data are available.

Maintenance of anaesthesia

Dosing guidelines for maintenance of anaesthesia in paediatric patients (1 - 12 years of age) (see Table 1 below).

Table 1: Dosing guidelines for maintenance of anaesthesia in paediatric patients (1 - 12 years of age)				
Concomitant anaesthetic medicine	Bolus infusion of ALTIMRE IV (µg/kg)	Continuous infusion of ALTIMRE IV (µg/kg/min)	Starting rate	Typical maintenance rates
Halothane (starting dose 0.3 MAC)	1	0.25	0.05 - 1.3	
Sevoflurane (starting dose 0.3 MAC)	1	0.25	0.05 - 0.9	
Isoflurane (starting dose 0.5 MAC)	1	0.25	0.06 - 0.09	

When given by bolus infusion, ALTIMRE IV should be administered over not less than 30 seconds. Surgery should not commence until at least 5 minutes after the start of ALTIMRE IV infusion. If a continuous bolus dose has not been given. Paediatric patients should be monitored, and the dose titrated to the depth of anaesthesia appropriate for the surgical procedure.

Concomitant medication

At the doses recommended above, remifentanyl significantly reduces the amount of hypnotic medicine required to maintain anaesthesia. Therefore, isoflurane, halothane and sevoflurane should be administered as recommended above to avoid excessive depth of anaesthesia. No data are available for dosage recommendations for simultaneous use of other hypnotics with remifentanyl.

Guidelines for discontinuation

Following discontinuation of the infusion, the offset of analgesic effect of ALTIMRE IV is rapid and similar to that seen in adult patients. Appropriate post-operative analgesic requirements should be anticipated and implemented (see Adults - Guidelines for discontinuation).

Neonates/infants (aged less than 1 year)

The pharmacokinetic profile of remifentanyl in neonates/infants (aged less than 1 year) is comparable to that seen in adults after correction of body weight differences.

However, there are insufficient clinical data to make dosage recommendations for this age group.

CARDIAC ANAESTHESIA

Adults (see Table 2 below)

Table 2: Cardiac anaesthesia Adults: Dosing guidelines for cardiac anaesthesia				
Indication	Bolus infusion of ALTIMRE IV (µg/kg)	Continuous infusion of ALTIMRE IV (µg/kg/min)	Starting rate	Typical infusion rates
Intubation	Not recommended	1	-	-
Maintenance of anaesthesia				
Isoflurane (starting dose 0.4 MAC)	0.5 - 1	1	0.005 - 4	
Propofol (starting dose 50 µg/kg/min)	0.5 - 1	1	0.01 - 4.3	

Continuation of post-operative analgesia, prior to extubation

It is recommended that the infusion of ALTIMRE IV should be maintained at the post-intra-operative rate during transfer of patients to the final operative care area. Upon arrival into the area, the infusion should be maintained initially at a rate of 1 µg/kg/min until the patient is ready to be weaned from the ventilator.

Guidelines for discontinuation

Prior to discontinuation of ALTIMRE IV, patients must be given alternative analgesic and sedative medicines at a sufficient time in advance. The choice and dose of medicines should be appropriate for the patient's level of post-operative care. It is recommended that the ALTIMRE IV infusion is discontinued by reducing the infusion rate in three to four steps of 50 % at 15 minute intervals. During weaning from the ventilator, the ALTIMRE IV infusion should not be increased, and only down titration should occur, supplemented as required with alternative analgesics. It is recommended that haemodynamic changes such as hypotension and tachycardia should be treated with alternative medicines, as appropriate.

Paediatric patients

There are insufficient data to make a dosage recommendation for use during cardiac surgery.

USE IN INTENSIVE CARE

ALTIMRE IV can be used for the provision of analgesia for up to 72 hours and as an aid to short-term sedation in mechanically ventilated intensive care patients.

It is recommended that ALTIMRE IV is initiated at an infusion rate of 0.1 (µg/kg/min (6 µg/kg/h)) - 0.15 (µg/kg/min (9 µg/kg/h)). The infusion rate should be increased to achieve the desired level of analgesia. A period of at least 5 minutes should be allowed between dose adjustments. The level of analgesia should be carefully monitored, regularly reassessed and the ALTIMRE IV infusion rate adjusted accordingly. If an infusion rate of 0.2 (µg/kg/min (1.5 µg/kg/h)) is reached and the desired level of sedation is not achieved, it is recommended that dosing with an appropriate sedative medicine is initiated (see below). The dose of sedative medicine should be titrated to obtain the desired level of sedation.

Further increases to the ALTIMRE IV infusion rate in increments of 0.025 (µg/kg/min (1.5 µg/kg/h)) may be made if additional analgesia is required.

Table 3 summarises the starting infusion rates and typical dose range for provision of analgesia and sedation in individual patients:

Table 3: Dosing guidelines for use of ALTIMRE IV within the intensive care setting		
Continuous infusion µg/kg/min (µg/kg/h)	Starting rate	Range
0.1 (6) - 0.15 (9)	0.006 (0.36) - 0.74 (44.4)	

Bolus doses of ALTIMRE IV are not recommended in the intensive care setting.

The use of ALTIMRE IV will reduce the dosage requirements of any concomitant sedative medicine by approximately 50 %.

Typical starting doses for sedative medicine, if required are given in Table 4 below.

Table 4: Recommended starting dose of sedative medicines, if required		
Sedative medicine (mg/kg)	Bolus (mg/kg)	Infusion (mg/kg/h)
Propofol	Up to 0.5	0.5
Midazolam	Up to 0.03	0.03

To allow separate titration of the respective medicines, sedative medicines should not be administered as an admixture.

Additional analgesia for ventilated patients undergoing stimulating procedures:
An increase in the existing ALTIMRE IV infusion rate may be required to provide additional analgesic cover for ventilated patients undergoing stimulating and/or painful procedures such as endotracheal suctioning, wound dressing and physiotherapy. It is recommended that an ALTIMRE IV infusion rate of at least 0.1 µg/kg/min (6 µg/kg/h) should be maintained for at least 5 minutes prior to the start of the stimulating procedure. Further dose adjustments may be made every 2 - 5 minutes in increments of 25 % - 50 % in anticipation of, or in response to, additional requirement for analgesia. A mean infusion rate of 0.25 µg/kg/min (1.5 µg/kg/h), maximum 0.75 µg/kg/min (4.5 µg/kg/h), has been administered for provision of additional analgesia during stimulating procedures.

Establishment of intra-venous analgesia prior to discontinuation of ALTIMRE IV
Due to the very rapid offset of action of ALTIMRE IV, no residual opioid activity will be present within 5 - 10 minutes after discontinuation regardless of the duration of infusion. Prior to discontinuation of ALTIMRE IV, patients must be given alternative analgesic and sedative medicines at a sufficient time in advance, to allow the therapeutic effects of these medicines to become established. It is therefore recommended that the choice of medicines, the dose and the time of administration, are planned prior to discontinuation of ALTIMRE IV.

Guidelines for extubation and discontinuation of ALTIMRE IV

In order to ensure a smooth emergence from an ALTIMRE IV-based regimen, it is recommended that the infusion of ALTIMRE IV is titrated in stages to 0.1 µg/kg/min (6 µg/kg/h) over a period up to 1 hour prior to extubation. Following extubation, the infusion rate should be reduced by 25 % decrements in at least 10 minute intervals until the patient is breathing spontaneously from the ventilator; the ALTIMRE IV infusion should not be increased, and only down titration should occur, supplemented as required with alternative analgesics.

Upon discontinuation of ALTIMRE IV, the IV cannula should be clamped or removed to prevent subsequent inadvertent administration. When other opioid medicines are administered as part of the regimen for transition to alternative analgesia, the patient must be carefully monitored. The benefit of providing adequate analgesia must always be balanced against the potential risk of respiratory depression with these medicines.

Paediatric intensive care patients

There are no data available on use in paediatric patients.

Renally impaired intensive care patients

No adjustments to the doses recommended above are necessary in renally impaired patients, including those undergoing renal replacement therapy.

Special populations

Elderly (over 65 years of age)

General anaesthesia

The initial starting dose of ALTIMRE IV should be half the recommended adult dose and then titrated to individual patient need, as an increased sensitivity to the pharmacological effects of remifentanyl has been seen in this patient population. This dose adjustment applies to use in all phases of anaesthesia including induction, maintenance and immediate post-operative analgesia.

Cardiac anaesthesia

No initial dose reduction is required (see above Cardiac Anaesthesia, Dosing guidelines).

Intensive care

No initial dose reduction is required (see Use in intensive care).

Obese patients

For obese patients (greater than 30 % over their ideal body weight) the dosage of ALTIMRE IV should be reduced and based upon ideal body weight, as the clearance and volume of distribution of remifentanyl are better correlated with ideal body weight than actual body weight in this population.

Renal impairment

No dosage adjustment is necessary in patients with impaired renal function, including intensive care patients.

Hepatic impairment

No dosage adjustment is necessary. However, patients with severe hepatic impairment may be more sensitive to the respiratory depressant effects of remifentanyl. These patients should be closely monitored and the dose of ALTIMRE IV titrated to individual patient need.

Neurosurgery

Limited clinical experience in patients undergoing neurosurgery has shown that no special dosage recommendations of ALTIMRE IV are required.

ASA (American society of anesthesiologists) II/IV patients

General anaesthesia

As the haemodynamic effects of potent opioids can be expected to be more pronounced in ASA II/IV patients, caution should be exercised in the administration of ALTIMRE IV in this population. Initial dosage reduction and subsequent hypotension may be effects therefore recommended.

Cardiac anaesthesia

No initial dose reduction is required (see Cardiac Anaesthesia: Dosing guidelines).

Long-term use in the intensive care unit (ICU)

No data are available on the long-term (longer than 72 hours) use of ALTIMRE IV in ICU patients.

Method of administration

After reconstitution, solutions of ALTIMRE IV are clear and colourless.

Continuous infusion of ALTIMRE IV must be administered by a calibrated infusion device into a fast-flowing IV line or via a dedicated IV line. This infusion line should be connected at, or close to, venous cannula and primed, to minimise the potential dead space.

Care should be taken to avoid obstruction or disconnection of infusion lines and to adequately clear the lines to remove residual ALTIMRE IV after use (see section 4.1).

ALTIMRE IV is for intravenous use only and must not be administered by epidural or intrathecal injection (see section 4.3).

Refer to section 6.6 for reconstitution instruction and further handling.

4.3 Contraindications

As glycine is present in the formulation, ALTIMRE IV is contraindicated for epidural and intrathecal use.

• hypersensitivity to remifentanyl, other fentanyl analogues or to any of the ingredients of ALTIMRE IV listed in section 6.1

• safety in pregnancy and lactation has not been established

• ALTIMRE IV should not be used with nitrous oxide and oxygen alone, at altitudes above sea level

• ALTIMRE IV should not be used unless artificial ventilation is planned.

4.4 Special warnings and precautions for use

ALTIMRE IV is not recommended for use as the sole medicine in general anaesthesia.

ALTIMRE IV should be administered only by persons specifically trained in the use of anaesthetic medicines and the recognition and management of the expected adverse effects of potent opioids, including respiratory and cardiac resuscitation such as the establishment and maintenance of a patent airway and assisted ventilation.

The use of ALTIMRE IV in mechanically ventilated intensive care patients is not recommended for a duration of treatment greater than 3 days.

Patients with a known hypersensitivity to opioids of a different class may exhibit a hypersensitivity reaction following administration of remifentanyl as in ALTIMRE IV. Caution should be exercised before using ALTIMRE IV in these patients.

Interference with daily activities may continue for up to 24 hours and no legal/contractual decisions should be entered into for 24 hours after receiving anaesthetic/conscious sedation. Alcohol use should also be avoided for the same time period.

Rapid offset of action/transition to alternative analgesia:
Due to the very rapid offset of action of ALTIMRE IV, no residual opioid activity will be present within 5 - 10 minutes after discontinuation of ALTIMRE IV. For those patients undergoing surgical procedures where post-operative pain is anticipated, analgesics should be administered prior to or immediately following discontinuation of ALTIMRE IV.

The possibility of tolerance, hyperalgesia and associated haemodynamic changes should be considered when used in the intensive care unit. Prior to discontinuation of ALTIMRE IV, patients must be given alternative analgesic and sedative medicines.

Sufficient time must be allowed to reach the maximum effect of the longer acting analgesic. The choice of analgesic, the dose and the time of administration should be planned in advance and individually tailored to be appropriate for the patient's surgical procedure and the level of post-operative care anticipated.

When other opioid agents are administered as part of the regimen for transition to alternative analgesia, the benefit of providing adequate post-operative analgesia must always be balanced against the potential risk of respiratory depression with these agents.

Risk from concomitant use of sedative medicines such as benzodiazepines or related medicines:
Concomitant use of remifentanyl as in ALTIMRE IV and benzodiazepines or related medicines such as benzodiazepines may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing with these sedative medicines should be reserved for patients for whom alternative treatment options are not possible. If a decision is made to prescribe ALTIMRE IV concomitantly with sedative medicines, the lowest effective dose should be used, and the duration of treatment should be as short as possible.

The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers to be aware of these symptoms (see section 4.5).

Discontinuation of treatment

Symptoms following withdrawal of remifentanyl as in ALTIMRE IV including tachycardia, hypertension and agitation have been reported infrequently upon abrupt cessation, particularly after prolonged administration of more than 3 days. The use of ALTIMRE IV in mechanically ventilated intensive care patients is not recommended for duration of treatment greater than 3 days.

Inadvertent administration

A sufficient amount of remifentanyl as in ALTIMRE IV may be present in the dead space of the IV line or in the cannula to cause respiratory depression, apnoea and/or muscle rigidity if the line is flushed with IV fluids or other medicines. This may be avoided by administering ALTIMRE IV into a fast-flowing IV line or via a dedicated IV line, which is adequately flushed of residual medicine, which is removed upon discontinuation of ALTIMRE IV.

Muscle rigidity: prevention and management

At the doses of remifentanyl as in ALTIMRE IV recommended, muscle rigidity may occur. The incidence is related to the dose and rate of administration. Therefore, bolus infusions should be administered over not less than 30 seconds.

Muscle rigidity induced by remifentanyl as in ALTIMRE IV must be treated in the context of the patient's clinical condition with appropriate supporting measures including ventilatory support. Excessive rigidity may be prevented during the induction of anaesthesia should be treated by the administration of a neuromuscular blocking medicine and/or additional hypnotic medicines.

Verbal rigidity seen during the use of remifentanyl as in ALTIMRE IV as an analgesic may be treated by stopping or decreasing the rate of administration of ALTIMRE IV.

Resolution of muscle rigidity after discontinuing the infusion of ALTIMRE IV occurs within minutes. Alternatively, an opioid antagonist may be administered, however this may reverse or attenuate the analgesic effect of remifentanyl.

Respiratory depression: management

Analgesia is accompanied by marked respiratory depression. Therefore, ALTIMRE IV should only be used in areas where facilities for monitoring and dealing with respiratory depression are available. The appearance of respiratory depression should be managed appropriately, including decreasing the rate of infusion by 50 % or a discontinuation of the infusion. Remifentanyl has not been shown to cause recurrent respiratory depression even after prolonged administration. However, as many factors may affect post-operative recovery it is important that full consciousness and adequate spontaneous ventilation are achieved before the patient is discharged from the recovery area. Patients with impaired lung function and with severe hepatic impairment are more sensitive to the respiratory depressant effects.

Cardiovascular effects

Hypotension and bradycardia, which can give rise to asystole and cardiac arrest (see section 4.5 and section 4.8), may be managed by reducing the rate of infusion of ALTIMRE IV or the dose of concurrent anaesthetics or by using IV fluids, vasopressor or anticholinergic medicines as appropriate. Dehydrated, hypovolaemic and elderly patients are more sensitive to the cardiovascular effects of remifentanyl, as in ALTIMRE IV.

Serotonin syndrome

Cases of serotonin syndrome, a potentially life-threatening condition, have been reported during concomitant use of remifentanyl with serotonergic medicines. Serotonergic medicines include selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), triocyclic antidepressants (TCAs), triptans, 5-HT₃ receptor antagonists, medicines that affect the serotonergic neurotransmitter system, and medicines that impair metabolism of serotonin (including MAO inhibitors, both those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue). This may occur within the recommended dosage range.

Serotonin syndrome symptoms may include mental status changes (e.g. agitation, hallucinations, coma), autonomic instability (e.g. tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g. hyperreflexia, incoordination), rigidity, and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea). The onset of symptoms generally occurs within several hours to a few days of concomitant use but may occur later than that. If serotonin syndrome is suspected, rapid discontinuation of remifentanyl should be considered.

Dependency

As with other opioids, remifentanyl as in ALTIMRE IV may produce dependency. There is an increased risk of addiction in patients with a personal or family history of substance abuse or mental health disorders.

Paediatric population

There is limited data available on use in neonates/infants under 1 year of age.

4.5 Interaction with other medicines and other forms of interaction

CNS depressant medicine
Remifentanyl as in ALTIMRE IV is not metabolised by plasma cholinesterase and therefore interactions with medicines metabolised by the enzyme are not anticipated. Remifentanyl decreases the doses of inhaled and IV anaesthetics and benzodiazepines required for anaesthesia.

If doses of concomitantly administered central nervous system (CNS) depressant medicines such as alcohol, anaesthetics, analgetics, hypnotics, or antipsychotics are not reduced, patients may experience an increased incidence of adverse effects associated with these medicines.

Other opioids

The concomitant use of opioids with sedative medicines such as benzodiazepines or related medicines increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dose and duration of concomitant use should be limited (see section 4.4).

Cardiac depressant medicine, (e.g. beta-blockers and calcium channel blocking agents)
The cardiovascular effect of remifentanyl as in ALTIMRE IV (hypotension and bradycardia) may be exacerbated in patients receiving concomitant cardiac depressant medicines, such as beta blockers and calcium channel blocking medicines.

Serotonergic medicine

Co-administration of remifentanyl such as ALTIMRE IV with medicine that affect the serotonergic neurotransmitter system has resulted in serotonin syndrome, a potentially life-threatening condition. Serotonergic medicines include selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), triocyclic antidepressants (TCAs), triptans, 5-HT₃ receptor antagonists, medicine that effect the serotonin neurotransmitter system (e.g. mirtazapine, trazodone, tramadol) and monoamine oxidase (MAO) inhibitors.

Caution should be exercised with concomitant use of MAOIs. Irreversible MAOIs should be discontinued at least 2 weeks prior to remifentanyl use.

Alcohol

After receiving ALTIMRE IV, it is advisable that alcoholic drink is avoided.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety of remifentanyl as in ALTIMRE IV in pregnancy and lactation has not been established and is therefore not recommended (see section 4.3).

Labour and delivery

The safety profile of remifentanyl as in ALTIMRE IV during labour or delivery has not been demonstrated. There are insufficient data to recommend remifentanyl as in ALTIMRE IV for use during labour and caesarean section. Remifentanyl, as in ALTIMRE IV, crosses the placental barrier and fentanyl analogues can cause respiratory depression in the child.

Breastfeeding

It is not known whether remifentanyl, as in ALTIMRE IV, is excreted in human milk. However, because fentanyl analogues are excreted in human milk and remifentanyl-related material was found in rat milk after dosing with remifentanyl, nursing mothers should be advised to discontinue breastfeeding for 24 hours following administration of ALTIMRE IV.

Fertility

There is no data on fertility with ALTIMRE IV.

4.7 Effects on ability to drive and use machines

Remifentanyl such as ALTIMRE IV has major influence on the ability to drive and use machines. The physician has to decide when these activities may be resumed.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **SE**

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
Remifentanyl
Sugar free. Preservative free.

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

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

What is in this leaflet

1. What ALTIREM IV is and what it is used for
2. What you need to know before you are administered ALTIREM IV
3. How ALTIREM IV is administered
4. Possible side effects
5. How to store ALTIREM IV
6. Contents of the pack and other information

1. What ALTIREM IV is and what it is used for
ALTIREM IV contains the active substance remifentanyl which belongs to a group of medicines called opioids. Remifentanyl starts to work quickly, and its effect lasts for a very short time.

Remifentanyl 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 (ICU).

2. What you need to know before you are administered ALTIREM IV
ALTIREM IV should not be administered to you:

- if you are hypersensitive (allergic) to remifentanyl 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 provider before you are 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 disorder, insomnia, epilepsy and alcohol dependence (see Other medicines and ALTIREM IV)
- you 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, 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 ALTIREM IV is administered

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 you are given ALTIREM IV, please consult your healthcare provider 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
- slower 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 other side effects not mentioned in this leaflet, please inform your doctor, nurse, pharmacist or other healthcare provider.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report any side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the 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 °C. Do not freeze. Keep the vial in the outer carton until required for use. Reconstituted solution: Store at 25 °C 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). Your doctor or nurse will throw away any medicine that is no longer required.

6. Contents of the pack and other information

What ALTIREM IV contains:
The active substance is remifentanyl. The reconstituted solutions of ALTIREM IV contain 1 mg per mL of remifentanyl as remifentanyl hydrochloride. ALTIREM IV 1 mg: Each single dose vial contains remifentanyl hydrochloride equivalent to 1 mg remifentanyl. ALTIREM IV 2 mg: Each single dose vial contains remifentanyl hydrochloride equivalent to 2 mg remifentanyl. ALTIREM IV 5 mg: Each single dose vial contains remifentanyl hydrochloride equivalent to 5 mg remifentanyl. 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 remifentanyl. 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, discoloration 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 °C) and further dilution to 20 - 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 use, 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, lyophilized powder. The powder is supplied in a clear, colourless glass vial. 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.

Pack size of 5 and 10 vials, packed in carton boxes.

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.

Pack size of 5 and 10 vials, packed in carton boxes.

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.

Pack size of 5 and 10 vials, packed in carton boxes.

Not all pack sizes are necessarily marketed.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, 7945

Cape Town, South Africa
Tel: +27 21 707 7000
or 0860-PHARMA (742 762)

This leaflet was last revised in

12 May 2025

Registration numbers

ALTIREM IV 1 mg: A52/2.9/0454
ALTIREM IV 2 mg: A52/2.9/0455
ALTIREM IV 5 mg: A52/2.9/0456

E6820	pharma  dynamics
PASIENTINLIETINGSBLAD SKEDULERINGSTATUS SE ALTIREM IV 1 mg poeler vir oplossing vir infusie/inspuiting ALTIREM IV 2 mg poeler vir oplossing vir infusie/inspuiting ALTIREM IV 5 mg poeler vir oplossing vir infusie/inspuiting Remifentanyl Sulkervry. Vry van preserveermiddels. Lees hierdie hele inligtingsblad deeglik deur, voordat ALTIREM IV aan u toegedien word • Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees. • Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegkundige, of ander gesondheidsorgverskaffer. Inhoud van hierdie inligtingsblad 1. Wat ALTIREM IV is en waarvoor dit gebruik word 2. Wat u nodig het om te weet, voordat ALTIREM IV aan u toegedien word 3. Hoe ALTIREM IV toegedien word 4. Moontlike newe-effekte 5. Hoe om ALTIREM IV te bewaar 6. Verpakkingsinhoud en ander inligting 1. Wat ALTIREM IV is en waarvoor dit gebruik word ALTIREM IV bevat die aktiewe bestanddeel remifentanyl, wat aan 'n groep medisyne wat opioïede genoem word, behoort. Remifentanyl se uitwerking is vinnig en die effek het 'n baie kort tydsduur. Remifentanyl is 'n sterk pynverligende medisyne, wat saam met verdovingsmedisyne (anestetika), gebruik word: • om u te help slaap voor 'n operasie • om u aan die slaap te hou en te verhoed dat u pyn tydens die operasie, ervaar • om u slaperig te maak en te verhoed dat u pyn ervaar, terwyl u behandeling in 'n intensiewe sorgseenheid, ontvang. 2. Wat u nodig het om te weet, voordat ALTIREM IV aan u toegedien word ALTIREM IV moet nie aan u toegedien word: • indien u hipersensitief (allergies) is vir remifentanyl of vir enige van die ander bestanddele van ALTIREM IV nie (sien afdeling 6), of vir medisyne van dieselfde klas (opioïede) nie • indien u hipersensitief (allergies) is vir enige ander pynverligende medisyne soortgelyk aan fentanyl en verwant aan die klas medisyne wat opioïede genoem word, of vir enige van die bestanddele van ALTIREM IV nie (sien afdeling 6). Opioïede word gebruik om akute pyn te behandel. Simptome van 'n allergiese reaksie kan lig of ernstig wees. Dit sluit gewoonlik sommige of almal van die volgende in: hyging, swelling van die lippe/mond, moontlike asemhaling, hooikoors, knoppies uitslag ("knoppies") of flou. • as inspuiting in die spinale kanaal nie • saam met sliktstofoksied en suurstof alleen op hoogtes bo seevlak nie • sonder kunsmatige asemhaling nie • indien u swanger is, of u babas borsvoed nie. Waarskuwings en voorsorgmaatreëls Vertel u dokter of gesondheidsorgverskaffer, voordat ALTIREM IV aan u toegedien word indien: • u allergies (hipersensitief) is vir enige ander opioïed medisyne, soos morfine of kodeïen • u enige kalmeermiddels soos bensodiasiepine (oor die algemeen gebruik om angstigheid, paniekversteurings, slaapprobleme, epilepsie en alkoholafhanklikheid te behandel), gebruik (sien ALTIREM IV) • u aan serotonien-sindroom ly. Indien u dokter kennis neem dat u serotonien-sindroom mag ontwikkel ('n potensieel lewensgevaarlike sindroom, sal die dokter besluit of die toediening van ALTIREM IV gestaak moet word. Tekens van serotonien-sindroom sluit hoë liggaamstemperatuur, hoë bloeddruk, vinnige hartklop, uitermatige gesweet, bewing, verwyding van u pupille, toename in refleksie, spierstreming, tremor, spierstijfheid, koördinasieverlies, daer-ervante krampe, gevoel van ongesteltheid, of koma. • u 'n operasie ondergaan, sal u dokter 'n alternatiewe pyn- of slaapmedikasie toedien, om enige pyn te beheer. Neem spesiale sorg met ALTIREM IV en vertel u dokter indien: • u 'n persoonlike-, of familiegeesteskiens van dwelmmisbruik, of geestesversteurings het (daar is 'n toenemende risiko vir verslawing) • u ouer as 65 jaar is, aangesien u die effek van ALTIREM IV oor 'n langer tydsduur mag ervaar • u gedehidreer is, baie bloed verloor het, of swak of ongesteel voel, aangesien daar 'n groter moontlikheid is dat u 'n effek op u hart mag ervaar (aie bloeddruk, of 'n harttempo wat stadiger as normaal voorkom) • u lewerprobleme het, aangesien ALTIREM IV u vermoed om asem te haal, mag aantas • u sorggewig is, aangesien u dokter die ALTIREM IV dosis mag verlaag • u aan 'n neuromuskulêre versteuring, wat spiere in u liggaam verswak wat verantwoordelik is vir beweging, ly. U mag meer prominente spierspanning, of -stijfheid ervaar, wat u asemhaling mag aantas • u aan 'n erge toestand ly wat gedeltes van u liggaam, of sels u hele liggaam aantas, soos swak beheerde diabetes, swak beheerde hoë bloeddruk, longversteurings, of hartprobleme • u aan 'n erge, lewensbedreigende toestand, soos swak beheerde versteurings, of eind-stadium leedsede, harttoestande, of nierversaking, ly. U moet geen wetlike besluite, of kontrakke teken, vir 24 uur nadat ALTIREM IV aan u toegedien is nie, aangesien hierdie medisyne met u daaglikse aktiwiteite mag inmeng. Indien u onseker is of enige van die bogenoemde op u van toepassing is, praat met u dokter, apteker, of verpleegkundige, voordat ALTIREM IV aan u toegedien word. Kinders ALTIREM IV moet nie aan babas jonger as 1 jaar oud toegedien word nie, aangesien dit waarskynlik nie veilig mag wees nie en daar beperkte inligting aangaande die gebruik van ALTIREM IV in hierdie ouderdomsgroep, beskikbaar is. Andere medisyne en ALTIREM IV Vertel altyd u gesondheidsorgverskaffer, indien u enige ander medisyne neem (Dit sluit aanvullende, of tradisionele medisyne in). Vertel u dokter, indien u enige van die volgende medisyne neem: • kalmeermiddels, of medisyne wat bensodiasiepine genoem word (gebruik om angstigheid, paniekaanvalle, slaapprobleme, epilepsie en alkoholafhanklikheid, te behandel), aangesien hierdie medisyne, die risiko vir lomerigheid, moontlike asemhaling (respiratoriese onderdrukking) en koma, mag verhoog en lewensgevaarlik mag wees. Geliktydigde gebruik, moet weens hierdie aspekte slegs ooreweg word, indien ander behandelingsopsies nie moontlik is nie. Indien u dokter eger ALTIREM IV saam met 'n kalmeermiddel voorskryf, moet die dosis en duur van die behandeling, deur u dokter beperk word • medisyne vir u hart, of bloeddruk, soos beta-blokkers (hierdie sluit atenolol, metoprolol, karvedilol, propranolol en bisoprolol in), of kalsiumkanaalblokkers (hierdie sluit amlodipine, diltiazem en nifedipien in), aangesien u effekte op u hart mag ervaar (aie bloeddruk, of 'n hartklop wat stadiger as normaal voorkom) • medisyne vir die behandeling van depressie, soos selektiewe serotonien heropname-inhibitors (SSRIs), serotonien noradrenalin heropname-inhibitors (SNRIs) en mono-amienskidsase-inhibitors (MAOIs). Daar word aanbeveel dat hierdie medisyne nie op dieselfde tydtyd as die medisyne geneem word nie, aangesien dit die risiko vir serotonien-sindroom, 'n potensieel lewensgevaarlike toestand, mag verhoog. ALTIREM IV saam met alkohol U moet alkohol vermy vir 24 uur nadat ALTIREM IV aan u toegedien is, aangesien 'n verhoging in newe-effekte mag ervaar (lomerigheid, moontlike asemhaling, of swangerskap, borsvoeding en fertiliteit Indien u swanger is of borsvoed, vermoed dat u swanger is, of 'n babas beplan, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgverskaffer vir advies, voordat ALTIREM IV aan u toegedien word. ALTIREM IV moet nie aan u toegedien word, indien u swanger is, of borsvoed nie (sien Wat u nodig het om te weet voordat ALTIREM IV aan u toegedien word). Bestuur en die hantering van masjiene ALTIREM IV het 'n groot invloed op die vermoë om te bestuur en masjiene te hanteer. Indien u slegs vir die dag in die hospitaal verblyf, sal u dokter u vertel vir hoe lank om te wag, voordat u die hospitaal mag verlaat, of 'n motor bestuur. Dit mag gevaarlik wees om te gou nadat u 'n operasie ondergaan het, te bestuur. ALTIREM IV mag u vermoed om te bestuur aantas, aangesien dit u slaperig, of duiselig mag laat voel. Moet nie bestuur, nadat ALTIREM IV aan u toegedien is, totdat u weet hoe dit u aantas nie. Dit is nie altyd moontlik om te voorspel tot watter mate ALTIREM IV met die daaglikse aktiwiteite van 'n pasiënt sal betrek nie. Pasiënte moet seker maak dat hulle nie by bogenoemde aktiwiteite betrokke raak, totdat hulle bewus is tot watter mate ALTIREM IV hulle aantas nie. 3. Hoe ALTIREM IV toegedien word Daar sal nie van u verwag word, om ALTIREM IV aan self toe te dien nie. Dit sal deur 'n gekwalifiseerde persoon aan u toegedien word. U dokter sal op die gepaste dosering vir u besluit. ALTIREM IV kan toegedien word: • as 'n enkel inspuiting in u aar • as 'n deurlopende infusie in u aar. Dit is wanneer ALTIREM IV stadig en oor 'n langer tydsduur aan u toegedien word. Die manier waarop ALTIREM IV aan u toegedien word en die dosis wat u ontvang, sal afhang van: • u gewig • die operasie wat u beplan • hoeveel pyn u sal ervaar • hoe vordief die mediese personeel van u verwag om te wees in die intensiewe sorgseenheid. Die dosis verskil van een pasiënt na die ander. Indien u meer ALTIREM IV ontvang as wat u behoort Aangesien 'n gesondheidsorgverskaffer ALTIREM IV aan u sal toedien, sal hy/zy die dosering beheer. In die geval van 'n oordosering, sal die dokter die oordosering hanteer. Die uitwerking van ALTIREM IV word deurgaans tydens u operasie, asook tydens intensiewe sorg, noukeurig gemonitor. Gepaste optrede sal onmiddellik gemaak word, indien u te veel ontvang. Nu u operasie Vertel u dokter of verpleegkundige indien u in pyn verkeer. Indien u pyn ervaar na u prosedure, sal hulle in staat wees om ander pynstillers vir u te gee.	4. Moontlike newe-effekte ALTIREM IV kan newe-effekte hê. Nie alle newe-effekte wat vir ALTIREM IV aangemeld is, word in hierdie inligtingsblad genoem nie. Sou u algemene gesondheid versleg, of indien u enige ongewenste effekte ervaar, tenwyl ALTIREM IV aan u toegedien word, raadpleeg asseblief u gesondheidsorgverskaffer vir advies. Indien enige van die volgende gebeur, sal ALTIREM IV toediening onmiddellik gestaak word: • swelling van die hande, voete, enkels, gesig, lippe, mond, of keel, wat sluk of asemhaling mag bemoeilik • uitslag of gejeuk • flou. Hierdie is alles ernstige newe-effekte. Indien u dit ervaar, kon u 'n ernstige allergiese reaksie vir ALTIREM IV gehad het, u mag dringende mediese aandag benodig. Vertel u dokter onmiddellik, indien u enige van die volgende opmerk: • hartklop wat stadiger as normaal voorkom, of ander hartprobleme • asemhaling hou op (apnee) • vlak of problematiese asemhaling (hipoksie) • fisiese drang vir ALTIREM IV (mediese afhanklikheid) of die behoefte vir 'n verhoging in dosis oor tyd, om dieselfde effek te verkry (medisyne-afhanksaamheid) • aanvalle (slipes), serotonien-sindroom. Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig. Vertel u dokter indien u enige van die volgende opmerk: Algemene newe-effekte: • hoë bloeddruk • lae bloeddruk (voel duiselig of lighoofdig) • hoës • naarsheid, braking • gejeuk • gewigstoename, abnormale lewerlogoetsresultate. Minder algemene newe-effekte: • hoofpyn • hardywigheid • lewerprobleme, abnormale bloetoevoerresultate, insluitend verhoogde cholesterolvlakke • boonste abdominale pyn • abdominale pyn wat die rug uitstraal • gevoeligheid, wanneer u die buik aanraak • koors • vinnige polsslag • naarsheid en braking. Andere newe-effekte wat u mag ervaar wanneer u wakker word, nadat u ALTIREM IV ontvang het, sluit die volgende in: Algemene newe-effekte: • bewing • verhoging in bloeddruk. Minder algemene newe-effekte: • voel baie kalm, of lomerig (sedasie) • aanhoudende, of voortdurende pyn • rusteloosheid (agitatie). Die volgende newe-effekte is aangemeld, maar die frekwensie van voorkoms is onbekend: • 'n tipe onreëlmatige hartklop (atrioventrikulêre blok) • medisyne afhanklikheid (fisiese drang vir ALTIREM IV) of medisyne toleransie (verdraagsaamheid (die behoefte vir toenemende doserings oor tyd, om dieselfde effek te verkry) • konvulsies (slipes), serotonien-sindroom. Indien u enige ander newe-effekte opmerk, wat nie in hierdie inligtingsblad genoem word nie, lig asseblief u dokter, verpleegkundige, apteker, of ander gesondheidsorgverskaffer in. Aanmelding van newe-effekte Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA via die Med Safety toepassing (Medsafety X SAHPRA) en eReporting platform (who-umc.org), wat op SAHPRA se webtuiste gevind kan word. Deur die aanmelding van newe-effekte, kan u help om meer inligting te verskaf. Vertel u dokter of ALTIREM IV u te win. U kan ook 'n epos direk aan die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za, om die veiligheid van die produk te verseker. 5. Hoe om ALTIREM IV te bewaar Bewaar alle medisyne buite die bereik van kinders. Bewaar teen of benede 25 °C. Moet nie vries nie. Hou die flesie in die buiteste kartonhouer, totdat dit benodig word vir gebruik. Hersaamgestelde oplossing: Bewaar teen 25 °C en gebruik binne 24 uur. Gooi enige ongebruikte oplossing weg. Moet nie ALTIREM IV gebruik, tensy dit 'n helder, kleurlose oplossing, vry van vreemde deeltjies, is nie. Moet nie gebruik na die vervaldatum wat op die kartonhouer aangedui word nie. Moet nie gebruik na die vervaldatum van 20 - 250 µg/mL (50 µg/mL is die aanbevole verdunning vir volwassenes en 20 - 25 µg/mL vir pediatriese pasiënte 1 jaar oud en ouer) met een van die volgende IV oplossings soos onder aangedui: • gesteriliseerde water vir inspuitings • 5 % dekstrose inspuiting • 5 % dekstrose en 0.9 % natriumchloried inspuiting • 0.9 % natriumchloried inspuiting • 0.45 % natriumchloried inspuiting. Doen 'n visuele ondersoek van die oplossing na verdunning, om te verseker dat dit helder, kleurloos en feitlik vry van vreemde deeltjies voorkom en dat die flesie nie beskadig is nie. Gooi enige oplossing weg, waar hierdie onreëlmatighede opgemerk word. ALTIREM IV moet nie met propofol, in dieselfde infusiesak gemeng word, voor toediening nie. ALTIREM IV moet nie in dieselfde infusielusyn met bloed/serum/plasma, toegedien word nie. ALTIREM IV moet nie met ander medisyne gemeng word, voor toediening nie. Hoe ALTIREM IV lyk en die verpakkingsinhoud ALTIREM IV is 'n steriele, endotoksien-vry, preserveermiddelvry, wit tot naaswit, vriesgedroogde poeler. Die oorsese verskaffer se gepaste vloeistof