

Applicant: Aspen SA Operations (Pty) Ltd
Product name: Remifentanil 5 Aspen
Dosage form and strength: Each vial contains 5 mg Remifentanil base as remifentanil hydrochloride

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1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S6

REMIFENTANIL 5 ASPEN 5mg Injection

Remifentanil

Contains 5 mg remifentanil base as remifentanil hydrochloride

Sugar Free

Read all of this leaflet carefully before REMIFENTANIL 5 ASPEN is administered to you

- 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.
- **REMIFENTANIL 5 ASPEN** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What REMIFENTANIL 5 ASPEN is and what it is used for

REMIFENTANIL 5 ASPEN belongs to a group of medicines called opioid anaesthetics.

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It is indicated as a narcotic analgesic or adjuvant for use during induction and/or maintenance of inhalational anaesthesia during surgical procedures including cardiac surgery.

It is also 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.

2. What you need to know before REMIFENTANIL 5 ASPEN is administered to you

REMIFENTANIL 5 ASPEN should not be administered to you:

REMIFENTANIL 5 ASPEN contains glycine and should therefore not be injected into the spinal cord (epidural or intrathecal).

- If you are hypersensitive (allergic) to remifentanil and/or opioids of a different class or any of the other ingredients of REMIFENTANIL 5 ASPEN (listed in section 6).
- If you have any airway disorders.
- If you are elderly patient with heart problems.
- If you are pregnant or breast feeding your baby as the safety in pregnancy and lactation has not been established.
- If you need to go for a medical procedure that requires nitrous oxide and oxygen alone at altitudes above sea level.
- Unless artificial ventilation is planned.

Warnings and precautions

Special care should be taken with REMIFENTANIL 5 ASPEN:

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Only those who are trained to give anaesthetic drugs and to recognize and manage the risks of strong opioids should give REMIFENTANIL 5 ASPEN. This includes knowing how to make sure the person breathes properly and how to give them extra oxygen.

- If you take sedative medicines such as benzodiazepines or related drugs along with REMIFENTANIL 5 ASPEN,
- If you discontinue REMIFENTANIL 5 ASPEN treatment, you may experience withdrawal syndrome.
- If you have muscle rigidity
- If you have respiratory depression
- If you have lowered blood pressure (hypotension) and a slower than normal heart rate (bradycardia).
- If you take opioids regularly, your body can become used to them and you can become dependent on them.
- If you need increasing doses over time to get the same effect (medicine tolerance).

Children and adolescents

There is no experience with REMIFENTANIL 5 ASPEN in children aged 1 to 12 years of age.

Other medicines and REMIFENTANIL 5 ASPEN

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 or will be receiving any of the following:

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- CNS depressant medicines such as alprazolam, diazepam, clonazepam used for sedation or to calm you down.
- Inhaled and IV anaesthetics, and benzodiazepines for anaesthesia usually administered during surgical procedures, as you may require a lower dose of these medicines.
- Medicines referred to as beta-blockers (such as propranolol or atenolol) and calcium channel blockers (such as verapamil and diltiazem) used to treat certain heart conditions.
- Medicines referred to as sedatives such as benzodiazepines (such as diazepam, clonazepam, alprazolam) or similar drugs used to treat anxiety, panic attacks, insomnia, seizures and alcohol dependence.
- Medicines referred to as Selective Serotonin Reuptake Inhibitors (SSRIs (such as fluoxetine or citalopram) and, Serotonin Norepinephrine Reuptake Inhibitors (SNRIs) (such as venlaxine) or Monoamine Oxidase Inhibitors (MAOIs)(such as selegiline, isocarboxazid, phenelzine or tranylcypromine). Concomitant use may result in serotonin syndrome, a potentially life-threatening condition. Your healthcare provider will inform you to stop using these medicines 2 weeks prior to REMIFENTANIL 5 ASPEN being administered to you.

Pregnancy, breastfeeding and fertility

You should not receive REMIFENTANIL 5 ASPEN if you are pregnant or breastfeeding your baby.

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 receiving REMIFENTANIL 5 ASPEN.

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Driving and using machines

REMIFENTANIL 5 ASPEN is expected to influence your ability to drive as it can make you sleepy. REMIFENTANIL 5 ASPEN will be administered to you in a hospital setting. If an early discharge is envisaged following REMIFENTANIL 5 ASPEN administration you should not drive, operate machinery or perform any tasks that require concentration.

It is not always possible to predict to what extent REMIFENTANIL 5 ASPEN may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which REMIFENTANIL 5 ASPEN affects you (see section 4).

3. How to use REMIFENTANIL 5 ASPEN

Do not share medicines prescribed for you with any other person.

You will not be expected to give REMIFENTANIL 5 ASPEN to yourself, it will be given to you by a person who is qualified to do so.

If you receive more REMIFENTANIL 5 ASPEN than you should

Since a healthcare provider will administer REMIFENTANIL 5 ASPEN, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

Symptoms include respiratory depression, slow resting heart rate (bradycardia), lowered blood pressure (hypotension), and skeletal muscle stiffness (skeletal muscle rigidity).

If you forget to use REMIFENTANIL 5 ASPEN

Since a healthcare provider will administer REMIFENTANIL 5 ASPEN, it is unlikely that the dose will be missed.

4. Possible side effects

REMIFENTANIL 5 ASPEN can have side effects.

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Not all side effects reported for REMIFENTANIL 5 ASPEN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using REMIFENTANIL 5 ASPEN, please consult your healthcare provider for advice.

If any of the following happens, REMIFENTANIL 5 ASPEN should be stopped. If you are in a hospital setting tell your doctor immediately or if you have been discharged, go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and 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 REMIFENTANIL 5 ASPEN. You may need urgent medical attention or hospitalisation.

If you are in a hospital setting tell your doctor immediately or if you have been discharged, go to the casualty department at your nearest hospital if you notice any of the following:

- Post-operative increase in blood pressure (hypertension).
- When your breaths are slower, shallower or stops and starts as these may be symptoms of airway suppression and/or apnoea (respiratory depression). This may be more prominent if you have liver problems.
- If you have symptoms like confusion, restlessness, difficulty breathing, rapid heart rate, and bluish skin, as these may be due to hypoxia (low levels of oxygen in the body tissues).

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- Sudden, unexpected loss of heart function, slow heartbeat, breathing and consciousness as these may be symptoms of cardiac arrest (when the heart stops suddenly).
- A problem with the rate or rhythm of your heartbeat. Your heart may beat too quickly, too slowly or with an irregular rhythm (dysrhythmia).
- Fits (convulsions).

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- High or low blood pressure (hypo/hypertension);
- cough;
- difficulty in passing stools (constipation);
- slow heartbeat (bradycardia);
- nausea, vomiting;
- itching of the skin (pruritus);
- Shivering following the operation.

The following side effects have been reported less frequently:

- Sleepiness (sedation) following the operation;
- post-operative aches.

The following side effects have been reported at an unknown frequency:

- medicine tolerance
- addiction to REMIFENTANIL 5 ASPEN
- withdrawal symptoms like agitation, anxiety, shaking or sweating, upon stopping taking REMIFENTANIL 5 ASPEN

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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 “6.04 Adverse Drug Reactions

Reporting Form”, found online under SAHPRA’s

publications: <https://www.sahpra.org.za/Publications/Index/8>

Aspen SA Operations (Pty) Ltd:

E-mail: saops.safety@aspenpharma.com

Tel: 0410040423

Toll Free Number: 08002337736

By reporting side effects, you can help provide more information on the safety of REMIFENTANIL 5 ASPEN.

5. How to store REMIFENTANIL 5 ASPEN

Store all medicines out of reach of children.

- Store at or below 25°C.
- Protect from light.
- Keep in original packaging until required for use.
- The reconstituted solution is stable for 24 hours at 25°C.

Do not store in a bathroom.

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

Return all unused medicine to your pharmacist.

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

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6. Contents of the pack and other information

What REMIFENTANIL 5 ASPEN contains

The active substance is 5 mg of Remifentanil.

The other ingredients are Glycine.

Sugar free

What REMIFENTANIL 5 ASPEN looks like and contents of the pack

REMIFENTANIL 5 ASPEN is white to off-white cake that may be intact or fragmented.

10 ml clear, Type 1 glass vials with grey bromobutyl rubber stoppers and secured with an aluminium overseal with a dark blue plastic flip-off top. The vials are placed in a cardboard carton together with a leaflet.

Holder of Certificate of Registration

ASPEN SA OPERATIONS (PTY) LTD

Corner of Fairclough Road &

Gibaud Road, Korsten

Gqeberha 6020

Hotline: 0800 118 088

This leaflet was last revised in

TBA

Registration number

Application number

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

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