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SCHEDULING STATUS

S6

Sufentanil 5 µg/ml 2 ml Viatris, solution for injection

Sufentanil 5 µg/ml 10 ml Viatris, solution for injection

Sufentanil 2 ml/10 ml, solution for injection

Sufentanil 5 µg/ml 2 ml Viatris:

Contains: Sodium chloride 900 mg with sodium content 7.08 mg per 2 ml.

Sufentanil 5 µg/ml 10 ml Viatris:

Contains: Sodium chloride 900 mg with sodium content 35,41 mg per 10 ml.

Sugar free

Read all of this leaflet carefully before you are given SUFENTANIL VIATRIS

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 SUFENTANIL VIATRIS is and what it is used for.

2. What you need to know before you use SUFENTANIL VIATRIS.

3. How to use SUFENTANIL VIATRIS.

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4. Possible side effects.

5. How to store SUFENTANIL VIATRIS.

6. Contents of the pack and other information.

1. What SUFENTANIL VIATRIS is and what it is used for

What SUFENTANIL VIATRIS is:

SUFENTANIL VIATRIS is a type of medicine called an opioid analgesic. The word opioid means a substance similar to opium, for instance strong pain reliever. An analgesic is a medicine that can be used to relieve pain.

What it is used for:

- SUFENTANIL VIATRIS is used to provide pain relief during surgical procedures and operations.
- SUFENTANIL VIATRIS is also used to provide pain relief in patients whose breathing must be assisted during surgery.

SUFENTANIL VIATRIS is administered by epidural route for:

- Post-operative pain management following general surgery, thoracic or orthopaedic operations and Caesarean sections.
- As an analgesic adjunct to epidural bupivacaine with or without epinephrine (adrenaline) during labour and vaginal deliveries.

2. What you need to know before you are administered SUFENTANIL VIATRIS

You or your child should not be administered SUFENTANIL VIATRIS:

- If you or your child are hypersensitive (allergic) to sufentanil or any of the other ingredients of SUFENTANIL VIATRIS.

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- If you or your child have previously had a hypersensitive (allergic) reaction to other strong pain relievers.
- If you are pregnant or breastfeeding.
- If you or your child have medical conditions such as severe bleeding or shock, blood poisoning, infection at the site of the injection, blood disorders where the epidural administration of SUFENTANIL VIATRIS cannot be used e.g. if you are taking an anticoagulant (a medicine used to prevent the formation of new blood clots).
- The safety and efficacy of epidural SUFENTANIL VIATRIS in children younger than 1 year have not been established.
- In order to avoid possible breathing problems in the new-born baby due to the medicine, SUFENTANIL VIATRIS should not be injected into a vein (intravenous use) during labour or during a caesarean section if the umbilical cord has not yet been cut. Injection around the spinal cord (epidural use), however, is safe for the newborn.
- If you or your child are taking, or has taken, monoamine oxidase inhibitors (MAOIs) used for depression, in the last 2 weeks.

Warnings and precautions

Special care should be taken with SUFENTANIL VIATRIS:

Tell your doctor or healthcare professional before being administered SUFENTANIL VIATRIS if you or your child:

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- Have breathing disorders or a lung disorder, such as asthma, bronchitis or emphysema. SUFENTANIL VIATRIS may weaken breathing. This may also occur sometime after the operation.
- Have any kind of heart disease (for instance heartbeat abnormalities, heart blocks or inadequate blood supply to the heart).
- Have blood pressure that is abnormally low.
- Have a problem with blood circulation in your brain.
- If you are elderly or weak due to ill health.
- Have a thyroid gland deficiency.
- Have a history of alcohol abuse.
- Have liver or kidney disorders.
- Check with your doctor before using SUFENTANIL VIATRIS with alcohol or other medicines that affect the central nervous system (CNS). The use of alcohol or other medicines that affect the central nervous system with SUFENTANIL VIATRIS may worsen the side effects of SUFENTANIL VIATRIS, such as dizziness, poor concentration, drowsiness, unusual dreams, and trouble with sleeping (see section '*Other medicines and SUFENTANIL VIATRIS*').

Elderly and debilitated patients:

- It is recommended to reduce the dosage in the elderly and in debilitated patients.

Children/ and adolescent

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- The safety and efficacy of epidural SUFENTANIL VIATRIS in paediatric patients younger than 1 year have not been established *(see' You or your child should not be administered SUFENTANIL VIATRIS').*

Other medicines and SUFENTANIL VIATRIS

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:

- Medicines used in surgery such as anaesthetics and muscle relaxants.
- Medicines to treat high blood pressure or medicines that could cause low blood pressure or water tablets.
- Medicines for anxiety or to help you sleep (e.g. benzodiazepines such as diazepam, lorazepam or midazolam).
- Medicines called 'beta-blockers' (for lowering of blood pressure).
- Buprenorphine which is a strong analgesic (for relief of severe pain).
- Cimetidine (medicine to treat stomach ulcers, heartburn or acid reflux).
- Erythromycin (antibiotic for treatment and prevention of infections).
- Medicines for treatment of depression e.g. monoamine oxidase Inhibitors (MAOI). These medicines should not be taken in the 2 weeks before SUFENTANIL VIATRIS is given.
- Nalbuphine or pentazocine (they belong to a group of medicines called analgesics and are used for the relief of moderate to severe pain).
- Naloxone (belongs to a group of medicines known as opioid antagonists. Opioid medicines are strong painkillers).

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- Naltrexone (for treatment of dependence on heroin, methadone and other similar (opiate medicines) substances of addiction).
- Nitrous oxide.
- Phenothiazines (to treat serious mental and emotional disorders including schizophrenia (a mental disorder that makes it difficult to tell the difference between real and unreal) and other psychotic disorders).
- Certain antiviral medicines used to treat HIV infection (e.g. ritonavir) or certain medicines for infections caused by fungi (e.g. ketoconazole, itraconazole). The dose of SUFENTANIL VIATRIS may need adjustment.

Remember to tell your doctor if you start taking any other medicines while you are receiving SUFENTANIL VIATRIS.

Receiving SUFENTANIL VIATRIS with food and drink and alcohol

You will be undergoing an operation and will therefore not eat or drink until you have fully recovered.

Tell your healthcare provider if you use alcohol regularly (*see section 'Take special care with SUFENTANIL VIATRIS'*)

Pregnancy and breastfeeding and fertility

- The safety of SUFENTANIL VIATRIS during pregnancy and whilst breastfeeding has not been established.
- 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 taking SUFENTANIL VIATRIS.

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- Your doctor will decide if you should be given SUFENTANIL VIATRIS. Take special care if you are receiving SUFENTANIL VIATRIS when breastfeeding your baby, because it may cause withdrawal symptoms in your baby when administration of SUFENTANIL VIATRIS is stopped, or when breastfeeding is stopped.
- If you have been given SUFENTANIL VIATRIS you should not breastfeed within 12 – 24 hours.
- If you are receiving SUFENTANIL VIATRIS for a long period, it may cause reduced fertility if you are a female and of childbearing potential, or if you are a male. It is not known whether these effects on fertility are reversible.

Driving and using machinery

It is not always possible to predict to what extent SUFENTANIL VIATRIS 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 SUFENTANIL VIATRIS affects them. VIATRIS may cause you to feel dizzy, light-headed and drowsy which could interfere with your ability to drive or use machines. Before driving a vehicle, operating a machine or making legal decisions, you should wait at least 24 hours after SUFENTANIL VIATRIS has been given. No alcohol should be consumed during this time.

When your SUFENTANIL VIATRIS treatment has stopped, ask your doctor when it will be safe for you to drive or use machines.

SUFENTANIL VIATRIS contains sodium

Sufentanil 5 µg/ml 2 ml Viatris:

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This medicine contains less than 1 mmol sodium (23 mg) per 2 ml that is to say essentially 'sodium free'.

Sufentanil 5 µg/ml 10 ml Viatris:

This medicine contains 35,41 mg sodium per 10 ml, equivalent to 1,77 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

SUFENTANIL VIATRIS is sugar free.

3. How to receive SUFENTANIL VIATRIS

- Do not share medicines prescribed for you with any other person.
- You will not be expected to give yourself SUFENTANIL VIATRIS. It will be given to you by a person who is qualified to do so.
- SUFENTANIL VIATRIS is given intravenously or as epidural administration.
- Your doctor will work out the dose of SUFENTANIL VIATRIS that you will need based on your age, weight, physical condition and other medicines that you are taking.
- If you have the impression that the effect of SUFENTANIL VIATRIS is too strong or too weak, tell your doctor or pharmacist.

If you receive more SUFENTANIL VIATRIS than you should:

Since a doctor will administer SUFENTANIL VIATRIS, it is unlikely that you will be given too much, as he/she will control the dosage.

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4. Possible side effects

SUFENTANIL VIATRIS can have side effects.

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

If any of the following happens, stop taking SUFENTANIL VIATRIS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing (abnormally slow and/or weak breathing or temporary cessation of breathing);
- skin rash, irregular skin patches and itching;
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Slow or absence of a heartbeat;
- chills or shivering or fever;
- feel dizzy, lightheaded, faint, very tired or weak, drowsy, confused;
- spasm of the breathing passages and vocal cords;

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- cardiac or respiratory arrest, disease in the electrical system of the heart (atrioventricular block), abnormal electrocardiogram;
- insufficient blood flow to the body tissues (shock), bluish discolouration of the skin or mucous membranes caused by lack of oxygen in the blood (including that of newborn);
- coma.

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:

- Headache;
- constipation;
- dry mouth;
- nausea, vomiting;
- sleepiness, a state of calm, lack of interest;
- neonatal tremor (jitters or trembling of the arms and legs);
- pale appearance;
- sudden muscle twitches;
- loss of bladder control.

The following side effects have been reported less frequently:

- Feeling of intense happiness, perception of hearing and seeing things, mood changes;

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- abnormal thinking, feeling anxious, sense of well-being, nervousness, problems with co-ordination, sensation of whirling and loss of balance, restlessness, loss of body temperature below normal;
- abnormal vision; visual disturbance, small pupils;
- abnormally rapid or irregular heartbeats;
- low or high blood pressure;
- stop of breathing for a short period of time ;
- facial flushing, sweating;
- muscle stiffness, repetitive body movements/muscle twitching;
- difficulty passing urine;
- hiccups;
- sneezing, itching, nasal discharge and congestion;
- pain, including back and injection site pain, and injection site reactions;
- excessive sweating, redness of the skin, rash (including of newborn), dry skin, discoloured skin;
- mild sleepiness may occur after administration around the spinal cord (epidural use).

The following side effect has been reported but the frequency is unknown:

- Decreased sexual desire or potency.

Post-marketing possible side effect:

The following side effect has been reported but the frequency is rare:

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- Increased risk of abdominal pain, including pancreatitis (with symptoms such as upper abdominal pain, nausea and vomiting).

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 on the SAHPRA website at: https://medsafety.sahpra.org.za/#download, via email at: adr@sahpra.org.za or via telephone at: 0125010311

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

5. How to store SUFENTANIL VIATRIS

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep the container in the outer carton until required for use.

Protect from light.

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).

For single use only or discard unused portion after initial opening.

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6. Contents of the pack and other information

What SUFENTANIL VIATRIS contains:

The active substance is sufentanil citrate equivalent to 5 µg/ml of sufentanil base

The other ingredients are hydrochloric acid solution (for pH adjustment), sodium hydroxide solution (for pH adjustment), sodium chloride and water for injection.

What SUFENTANIL VIATRIS looks like and contents of the pack:

What SUFENTANIL VIATRIS looks like:

A clear colourless solution.

Free from visible foreign material.

Contents of the pack:

SUFENTANIL VIATRIS is supplied in a clear colourless Type I ampoule.

10 x 2 ml and 10 x 10 ml ampoules are packed in a polystyrene container or a carton.*

*Not all packs may be marketed.

Holder of Certificate of Registration and Manufacturer

Viatris South Africa (Pty) Ltd

4 Brewery Street

Isando

Johannesburg, 1609

Republic of South Africa

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This leaflet was last revised in

Date of publication: 17 November 2014

Date of revision of text: TBA

Registration number

Sufentanil 5 µg/ml 2 ml Viatris Solution for Injection: 41/2.9/0625

Sufentanil 5 µg/ml 10 ml Viatris Solution for Injection: 41/2.9/0626

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.