

Approved Patient Information Leaflet for SUFENTA FORTE®**PATIENT INFORMATION LEAFLET****SCHEDULING STATUS** S6**SUFENTA FORTE® solution for injection or infusion****Each mL contains 50 µg sufentanil as sufentanil citrate.**

For IV or epidural use.

Sugar free.

Read all of this leaflet carefully before you or your child receive SUFENTA FORTE.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or health care provider.
- SUFENTA FORTE has been prescribed for you or your child.

What is in this leaflet

1. What SUFENTA FORTE is and what it is used for
2. What you need to know before you or your child is administered SUFENTA FORTE
3. How to receive SUFENTA FORTE
4. Possible side effects
5. How to store SUFENTA FORTE
6. Contents of the pack and other information.

1. What SUFENTA FORTE is and what it is used for

The actual medicine in SUFENTA FORTE is sufentanil. It is a strong painkiller of the opioid type.

It is used in hospitals where the correct safety precautions can be taken.

Each mL contains 50 µg sufentanil as sufentanil citrate.

When injected into a vein, SUFENTA FORTE also strengthens the state of general loss of feeling (narcosis or anaesthesia). This is useful in surgical procedures.

SUFENTA FORTE can be used for both general and regional anaesthesia:

- in general anaesthesia, SUFENTA FORTE is injected into a vein (intravenous use).
- in regional anaesthesia, SUFENTA FORTE is injected around the spinal cord (epidural use).
This technique is used, for instance, in childbirth or in the treatment of post-operative pain.

2. What you need to know before you or your child is administered SUFENTA FORTE

You or your child should not be administered SUFENTA FORTE:

- If you or your child is hypersensitive (allergic) to sufentanil or any of the other ingredients of SUFENTA FORTE or a similar painkiller, e.g. opioids (see section 6 for other ingredients).
- In order to avoid possible breathing problems in the newborn baby due to the medicine, SUFENTA FORTE 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.
- SUFENTA FORTE should not be injected around the spinal cord (epidural use) if there is shock, severe bleeding, systemic infection or inflammation around the injection site.
- SUFENTA FORTE should not be injected epidurally if you are taking certain medicines, for example anticoagulants (used to prevent the formation of new blood clots).
- If you or your child is taking, or has taken, monoamine oxidase inhibitors (MAOIs) used for depression, in the last 2 weeks.

Warnings and precautions

Take special care with SUFENTA FORTE:

Important!

SUFENTA FORTE is a strong painkiller and should be given only by competent persons.

SUFENTA FORTE may weaken breathing. This may also occur sometime after the operation.

Therefore, you or your child will remain under supervision for a while after the operation. If you or your child experiences severe drowsiness or breathing problems, tell a doctor or nurse immediately.

Let your doctor know if you or your child has a lung disease or breathing problems, brain disorder, impaired thyroid, liver or kidney function; slow pulse, low blood pressure, or takes or has taken strong painkillers.

Stiffness of muscles or involuntary twitching may occur with the use of SUFENTA FORTE.

Elderly and debilitated patients

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

Paediatric population

Safety and efficacy of intravenous SUFENTA FORTE in children younger than 1 month have not been established.

Other medicines and SUFENTA FORTE:

Always tell your health care provider if you or your child is taking any other medicine. (This includes all complementary or traditional medicines.)

You should always inform your doctor if you or your child is taking other medicines since a number of medicines should not be combined with SUFENTA FORTE. Occasionally, it is necessary to adapt the dose in the case of combined use.

Tell your doctor if you or your child is taking other medicines because some other medicines should not be taken with SUFENTA FORTE. These may include:

- Certain medicines for depression called MAOIs should not be combined with SUFENTA FORTE. These medicines should not be taken in the 2 weeks before SUFENTA FORTE is given.
- If you or your child has been taking other strong painkillers for a long time, you should mention this to your doctor. The dose may have to be adjusted.
- You should also inform your doctor if you or your child uses alcohol or drugs regularly or if you or your child is taking a medicine that slows up your reactions (for example, sleeping pills, tranquillisers, medicine for mental disorders).
- Your doctor will need to know if you or your child is using certain antiviral medicines used to treat HIV infection (AIDS) (e.g. ritonavir) or certain medicines for infections caused by fungi (e.g. ketoconazole, itraconazole). The dose of SUFENTA FORTE may need adjustment.

SUFENTA FORTE with alcohol:

Tell your health care provider if you or your child uses alcohol regularly, because the dose may need to be changed.

Pregnancy and breastfeeding:

If you are pregnant, you should inform your doctor, who will decide if you should be given SUFENTA FORTE into a vein (intravenous use). For pain during labour and birth SUFENTA FORTE should be given only around the spinal cord (epidural use).

If you are breastfeeding or wish to do so, it is better to discuss this first with your doctor. He will give you the best advice, based on the amount of SUFENTA FORTE and the way in which it is given.

Driving and using machines:

SUFENTA FORTE may have a negative effect on alertness or driving ability. Before driving a vehicle, operating a machine or making legal decisions, you should wait 24 hours after SUFENTA FORTE has been given. No alcohol should be consumed during this time. Always ask your doctor's advice first.

3. How to use SUFENTA FORTE

SUFENTA FORTE is injected: either into a vein (intravenous use) for anaesthesia of the whole body, or at a certain level around the spinal cord (epidural use) for anaesthesia of a part of the body.

The dose of SUFENTA FORTE and the way in which it is given depend on the situation. Your doctor will determine how much SUFENTA FORTE you or your child needs on the basis of your body mass, age and medical condition.

For administration around the spinal cord (epidural use), a fine tube is inserted through which SUFENTA FORTE is administered. Several doses can be given through this small tube, depending on the requirements.

You will not be expected to give yourself or your child SUFENTA FORTE. It will be given to you or your child by a person who is qualified to do so.

If you or your child receives more SUFENTA FORTE than should be received:

Since a health care provider will administer SUFENTA FORTE, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

The main symptom is markedly weakened breathing.

4. Possible side effects

SUFENTA FORTE can have side effects.

Not all side effects reported for SUFENTA FORTE are included in this leaflet. Should you or your child's general health worsen or if you or your child experiences any untoward effects while receiving SUFENTA FORTE, please consult your doctor, pharmacist or other health care provider for advice.

Undesired effects, if any, occur mainly during the operation and are managed by your doctor.

Some may also occur shortly afterwards; therefore, you will remain under supervision for a while after the operation.

If any of the following happens, stop receiving SUFENTA FORTE and tell your doctor immediately:

- 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 or your child has them, you or your child may have had a serious reaction to SUFENTA FORTE. You or your child may need urgent medical attention.

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

- abnormally slow and/or weak breathing or temporary cessation of breathing
- spasm of the breathing passages and voice box
- slow, fast or irregular heartbeat
- convulsions
- cardiac or respiratory arrest; disorder 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 of newborn)
- coma.

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

Tell your doctor as soon as possible if you notice any of the following:

- hiccups
- low or high blood pressure
- muscle stiffness or involuntary muscle movements (including slow, stiff or jerking movements – including of newborn)
- sudden muscle twitches
- decreased (in newborn), increased or abnormal muscle tone
- dizziness
- nausea and vomiting
- headache
- nervousness, sleepiness, sedation, lack of interest
- fluid in the lungs; sneezing, itching, nasal discharge and congestion; cough; hoarseness
- paleness
- chills, fever, increased or decreased body temperature
- visual disturbance, small pupils
- urinary retention or incontinence
- 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 or itching may occur after administration around the spinal cord (epidural use).

Side effects in children

Frequency, type and severity of adverse reactions are expected to be the same as in adults.

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

Reporting of side effects:

If you or your child gets side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the “**Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of SUFENTA FORTE.

5. How to store SUFENTA FORTE

- Store at or below 25 °C. Protect from light.
- Your doctor will store SUFENTA FORTE and will not keep it after the expiry date (month and year) printed after “EXP”.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What SUFENTA FORTE contains:

The active substance in SUFENTA FORTE is sufentanil.

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

What SUFENTA FORTE looks like and contents of the pack:

A clear colourless solution, free from visible foreign material.

Cartons containing 5 x 5 mL ampoules.

Holder of Certificate of Registration:

Piramal Critical Care South Africa (Pty) Ltd

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