**Approved Patient Information Leaflet for**

**FENTANYL 500 µg/10 mL FRESENIUS and FENTANYL 100 µg/2 mL**

**FRESENIUS**

## SCHEDULING STATUS

**S6**

# FENTANYL 500 µg/10 mL FRESENIUS

# FENTANYL 100 µg/2 mL FRESENIUS

**Solution for injection**

**Fentanyl**

**Sugar free.**

**Read all of this leaflet carefully before you are given FENTANYL FRESENIUS**

- 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 FENTANYL FRESENIUS is and what it is used for
2. What you need to know before you are given FENTANYL FRESENIUS
3. How to receive FENTANYL FRESENIUS
4. Possible side effects
5. How to store FENTANYL FRESENIUS
6. Contents of the pack and other information.

## 1. What FENTANYL FRESENIUS is and what it is used for

The active ingredient in FENTANYL FRESENIUS is fentanyl and it belongs to a group of medicines called opioid analgesics.

FENTANYL FRESENIUS a strong painkiller, used in anaesthesia or to relieve serious pain during/after surgical procedures/operations.

## 2. What you need to know before you are given FENTANYL FRESENIUS

**FENTANYL FRESENIUS should not be given to you:**

- if you are hypersensitive (allergic) to fentanyl or to other opioids
- if you have any problems that affect your breathing including chronic bronchitis or emphysema
- if you've just had an operation of the gallbladder or bile ducts
- if you are under the influence of alcohol
- if you have a head injury or increased pressure inside the skull
- if you are having an asthma attack
- if you have heart failure in addition to lung disease
- if you are taking medicines used to treat depression, called mono-amine oxidase inhibitors, or within 14 days of stopping such treatment
- to babies less than one year old, before an operation
- if you suffer from fits
- if you are in a coma.

**Warnings and precautions**

**Tell your doctor or healthcare provider before being given the injection:**

**Take special care with FENTANYL FRESENIUS:**

- if you have lung problems or asthma

- if you have liver or kidney problems
- if you have heart problems
- if you have low or high blood pressure
- if you've lost a lot of blood
- if your body is in shock, i.e. your organs are not getting enough blood or oxygen
- if you are elderly or weak
- if you have an uncontrolled underactive thyroid gland
- if you are an alcoholic
- if your adrenal glands produce too little of a certain hormone
- if you have an enlarged prostate
- if you have myasthenia gravis, a condition causing abnormal muscle weakness
- if you or anyone in your family have ever abused or been dependant on alcohol, prescription medicines or illegal drugs (addiction")
- if you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- if you are a smoker
- if you ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses
- repeated use of opioid painkillers may result in the medicine being less effective (you become accustomed to it). It may also lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on FENTANYL FRESENIUS, it is important that you consult your doctor.

**Children**

If FENTANYL FRESENIUS is given to the mother during childbirth (including caesarean section), it may cause breathing difficulties in the newborn baby. Babies born to mothers who are addicted to FENTANYL FRESENIUS may suffer withdrawal symptoms.

**Other medicines and FENTANYL FRESENIUS**

**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 using any of the following medicines:**

- Antibiotics used to treat infection such as ciprofloxacin or erythromycin.
- Antifungal medicines such as fluconazole, itraconazole, ketoconazole or voriconazole.
- Diltiazem, used for high blood pressure or heart problems.
- Medicines that suppress the central nervous system such as barbiturates, benzodiazepines (e.g., midazolam), tricyclic antidepressants, sedatives, phenothiazines, hypnotics, meprobamate, anxiolytics, antipsychotics, opioid pre-medication, neuroleptics (e.g., droperidol), general anaesthetics (e.g., etomidate) and halogenic gases. These medicines might cause breathing difficulties when used with FENTANYL FRESENIUS.
- Medicines for heartburn and stomach problems such as cimetidine or cisapride.
- Medicines for nausea such as cyclizine, metoclopramide or domperidone.
- Mexiletine, used to treat certain heart conditions.
- Muscle relaxants.
- Ritonavir, used for HIV.
- Medicines used to treat depression, called mono-amine oxidase inhibitors. These medicines should not be combined with FENTANYL FRESENIUS or taken in the 14 days before FENTANYL FRESENIUS is given (see “**FENTANYL FRESENIUS should not be given to you**”).

- Other medicines used to treat depression, called selective serotonin re-uptake inhibitors (SSRIs) or serotonin norepinephrine re-uptake inhibitors (SNRIs).

Please ask your doctor or healthcare provider if you are unsure about your medicine.

**Pregnancy and breastfeeding**

Safety in pregnancy and breastfeeding has not been established.

If FENTANYL FRESENIUS is given to the mother during childbirth (including caesarean section), it may cause breathing difficulties in the newborn baby. Babies born to mothers who are addicted to FENTANYL FRESENIUS may suffer withdrawal symptoms.

FENTANYL FRESENIUS is found in breast milk and may cause drowsiness or breathing difficulties in breastfed babies. Breastfeeding is not recommended for 24 hours after receiving FENTANYL FRESENIUS.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist of other healthcare provider for advice before receiving FENTANYL FRESENIUS.

**Driving and using machines**

FENTANYL FRESENIUS can cause drowsiness and clouding of consciousness which could interfere with your ability to drive or to use machinery.

Do not drive or use machines within 24 hours of receiving FENTANYL FRESENIUS.

## 3. How to receive FENTANYL FRESENIUS

As FENTANYL FRESENIUS is an injection, it will be administered by your doctor or healthcare provider.

Your doctor will choose the most suitable dose for your particular condition and for how long you will be receiving this medicine. Your doctor will determine how much FENTANYL FRESENIUS you need based on your body mass, age and medical condition.

If you have the impression that the effect of FENTANYL FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

FENTANYL FRESENIUS may be given by injection into a vein (intravenous).

You will not be expected to give yourself FENTANYL FRESENIUS. It will be given to you by a person who is qualified to do so.

**If you receive more FENTANYL FRESENIUS than you should**

Since a healthcare provider will administer FENTANYL FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.
A brain disorder (known as toxic leukoencephalopathy) can be a symptom of overdosage.

**If you forget to receive FENTANYL FRESENIUS**

Since a healthcare provider will administer FENTANYL FRESENIUS, it is unlikely that the dose will be missed.

## 4. Possible side effects

FENTANYL FRESENIUS can have side effects.

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

If any of the following happens, stop receiving FENTANYL FRESENIUS 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.
- Suppression of breathing, tight chest or airways, rapid or deep breathing, inability to breathe.
- Fits (convulsions), loss of consciousness, increased pressure inside the skull.
- Heart attack.

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

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

*Frequent side effects:*

- Agitation (anxiety or nervous excitement).
- Dizziness, drowsiness, sedation.
- Feeling confused when waking up after the operation.
- A feeling that the world is spinning (vertigo).
- Nausea (feeling sick), vomiting (being sick).
- Constipation (difficulty passing stools).
- Stiffness or uncontrolled contraction/movement of muscles.

- Excessive constriction of the pupil of the eye (small pupils), visual disturbances.
- Skin rash or irritation.
- Slow, fast or irregular heartbeat.
- Low or high blood pressure.
- Vein pain.

*Less frequent side effects:*

- Headaches, hallucinations, confusion.
- Mood changes, intensely happy mood.
- Feeling agitated when waking up after the operation.
- Drug withdrawal syndrome.
- Stomach pain.
- Hiccups.
- Blood pressure fluctuation.
- Inflammation of a vein.
- Difficulty passing urine.
- Chills, feeling cold.
- Itchy skin.
- Abdominal pain, including inflamed and irritated pancreas.

*Side effects with an unknown frequency:*

- Confused thinking and reduced awareness of the environment.
- Drug dependence (addiction).
- Restlessness.
- A pounding heartbeat.
- Reduced amounts of urine, pain in the lower abdomen.
- Dry mouth, sweating, facial flushing.

- A decrease in sex drive.
- Difficulty in swallowing.

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 via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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

## 5. How to store FENTANYL FRESENIUS

- FENTANYL FRESENIUS will be stored in a pharmacy or in the hospital wards.
- Store all medicines out of reach of children.
- FENTANYL FRESENIUS should not be used after the expiry date printed on the ampoule or carton.
- FENTANYL FRESENIUS should be stored at or below 30 °C and protected from light.
- If only part of the contents of an ampoule is used, the remaining solution should be discarded.
- For single use only.

## 6. Contents of the pack and other information

**What FENTANYL FRESENIUS contains**

The active substance is fentanyl.

Each 10 mL contains the equivalent of 500 microgram (µg) fentanyl base as fentanyl citrate.

Each 2 mL contains the equivalent of 100 microgram (µg) fentanyl base as fentanyl citrate.

The other ingredient is water for injection.

Sugar free.

**What FENTANYL FRESENIUS looks like and contents of the pack**

A clear, colourless solution.

10 mL Amber ampoules with a white ring above the neck and packed in containers each containing 5 ampoules.

2 mL Amber ampoules with a white ring above the neck and packed in containers each containing 10 ampoules.

**Holder of Certificate of Registration**

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**This leaflet was last revised on**

23 October 2025.

**Registration numbers**

FENTANYL 500 µg/10 mL FRESENIUS: X/2.7/260

FENTANYL 100 µg/2 mL FRESENIUS: W/2.9/123

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|---|---|---|
| Botswana: | 100 µg/2 mL | BOT1001705, [S1A] |
| Namibia: | 100 µg/2 mL | [NS4] 90/2.9/00442 |
| Zambia: | 100 µg/2 mL | 254/006, POM |
| Zimbabwe: | 100 µg/2 mL | 2006/4.1/4435, N (4.1 Narcotic analgesic) |