SCHEDULING STATUS

S6

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Fentanyl Fresenius 500 mcg/10 ml

Fentanyl base 500 µg per 10 ml

Fentanyl Fresenius 100 mcg/2 ml

Fentanyl base 100 µg per 2 ml

Injection

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 or your pharmacist.
- **Fentanyl Fresenius** has been prescribed for you personally.

WHAT FENTANYL FRESENIUS CONTAINS

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 ingredients are: nitrogen, water for injection.

Sugar free.

WHAT FENTANYL FRESENIUS IS USED FOR

Fentanyl Fresenius is a narcotic analgesic used to relieve pain during surgical procedures/operations under anaesthesia.

BEFORE YOU ARE GIVEN FENTANYL FRESENIUS

Fentanyl Fresenius should not be given if you:

- are sensitive or allergic to **Fentanyl Fresenius** or other ingredients in this product
- have any problems that affect your breathing including chronic bronchitis or emphysema
- are taking medicines used to treat depression.

Take special care with Fentanyl Fresenius:

- as it can cause drowsiness and clouding of consciousness which could interfere with your ability to drive or to use machinery;
- as it can become less effective with repeated use (tolerance) and this means an increase in dosage is required for **Fentanyl Fresenius** to remain effective, repeated use of **Fentanyl Fresenius** becomes habit-forming (dependence) and unpleasant withdrawal symptoms may occur with the sudden stop of **Fentanyl Fresenius** treatment.

Pregnancy and breastfeeding

Do not use **Fentanyl Fresenius** if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving **Fentanyl Fresenius**.

Using other medicines with Fentanyl Fresenius:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

HOW FENTANYL FRESENIUS IS GIVEN

As **Fentanyl Fresenius** is an injection, it will be administered by your doctor or healthcare professional.

Dosage:

Your doctor will choose the most suitable dose for your particular condition and for how long you will be receiving this medicine for.

If you have an impression that the effects of **Fentanyl Fresenius** is too strong or too weak, tell your doctor or pharmacist.

Method of administration:

Fentanyl Fresenius may be administered by injection into a muscle (intramuscularly) or by injection or infusion 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 have received more Fentanyl Fresenius than you should:

Since a healthcare professional will administer **Fentanyl Fresenius**, he/she will control the dosage. However in the event of overdosage your doctor will manage the overdosage.

POSSIBLE SIDE EFFECTS

Fentanyl Fresenius can have side effects:

- Dizziness, nausea (feeling sick), vomiting (being sick), or constipation
- Stomach pain and headaches
- Mood changes, or a decrease in sex drive
- Stiffness or contraction of muscles
- Suppression of breathing

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 doctor, pharmacist or other healthcare professional for advice.

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

STORING AND DISPOSING OF FENTANYL FRESENIUS

- **Fentanyl Fresenius** will be stored in pharmacy or in the hospital wards.

- Keep 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 protected from light and stored at or below 25 ˚C.
- If only part of the contents of an ampoule is used, the remaining solution should be discarded.
- For single use only.

PRESENTATIONS OF FENTANYL FRESENIUS

10 ml amber ampoules with a white ring above the neck and packed into blister trays into cardboard cartons in packs of 5.

2 ml amber ampoules with a white ring above the neck and packed into blister trays into cardboard cartons in packs of 10.

IDENTIFICATION OF FENTANYL FRESENIUS

Clear, colourless solution in amber glass ampoules.

REGISTRATION NUMBERS

Fentanyl Fresenius 500 mcg/10 ml: X/2.7/260

Fentanyl Fresenius 100 mcg/2 ml: W/2.9/123

NAME AND ADDRESS OF REGISTRATION HOLDER

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten

Port Elizabeth

South Africa

6020

Telephone no.: +27 (0)41 – 403 1600

DATE OF PUBLICATION

Date of registration: 01 June 1990 (Fentanyl Fresenius 500 mcg/10 ml

11 April 1989 (Fentanyl Fresenius 100 mcg/2 ml)

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