**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

**S6**

**PROPRIETARY NAMES, STRENGTH AND PHARMACEUTICAL FORM**

**PETHIDINE HCl 25 mg/1 mL FRESENIUS**

**PETHIDINE HCl 50 mg/1 mL FRESENIUS**

**PETHIDINE HCl 100 mg/2 mL FRESENIUS**

Injection

**Read the entire leaflet carefully before you are given PETHIDINE FRESENIUS**

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or your pharmacist.
- PETHIDINE FRESENIUS has been prescribed for you personally.

## 1, WHAT PETHIDINE FRESENIUS CONTAINS

**Active ingredient:**

Each 1 mL clear glass ampoule contains either 25 mg or 50 mg pethidine hydrochloride, whereas the 2 mL clear glass ampoule contains 100 mg pethidine hydrochloride.

**Inactive ingredients**:

Water for injection, hydrochloric acid (traces).

## 2. WHAT PETHIDINE FRESENIUS IS USED FOR

PETHIDINE FRESENIUS belongs to a group of medicines called opioid (narcotic) analgesics. It works by blocking the pain signals from reaching your brain.

PETHIDINE FRESENIUS is used for the relief of pain. It is particularly useful for the control and relief of pain after you have had an operation. It may be used when you are in labour for the relief of labour pains.

## 3. BEFORE YOU RECEIVE PETHIDINE FRESENIUS

**You should not be administered PETHIDINE FRESENIUS:**

- if you are hypersensitive (allergic) to pethidine or any of the other ingredients of PETHIDINE FRESENIUS.

Tell your doctor if you have had an allergic reaction to PETHIDINE FRESENIUS or any other medicines or other substances, such as foods, preservatives or dyes. This may include medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Special care should be taken with PETHIDINE FRESENIUS**

PETHIDINE FRESENIUS should not be administered, or administered to you with caution, if you have any of the following conditions:

- Lung disease, difficulty in breathing, asthma
- Tumour within your adrenal glands
- For pain relief after a gall bladder operation
- Relief of pain associated with kidney stones
- Alcoholism
- Suffer from convulsions
- Head injuries
- Increased pressure within the head
- Suffer from hypothyroidism
- Corticosteroid deficiency
- Impaired liver or kidney function

- Enlarged prostrate
- Low blood pressure
- Shock
- Muscle weakness
- Bowel disorders.

**Pregnancy and breastfeeding:**

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

**Using other medicines with PETHIDINE FRESENIUS:**

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

Some medicines and PETHIDINE FRESENIUS may interfere with each other. Tell your doctor if you are taking or receiving any other medicine, including a non-prescription medicine that you may have purchased from your pharmacy. These include:

- Phenothiazines
- Monoamine oxidase inhibitors, or within 2 weeks of stopping such treatment
- Alcohol
- Hypnotics (sleeping tablets)
- Tricyclic antidepressants
- Medicines for the treatment of psychotic disorders, such as schizophrenia and paranoia
- Cyclizine, medicine for the treatment of motion sickness, dizziness and nausea
- Phenytoin – used for the treatment of epilepsy

- Cimetidine – reduces the production of gastric acid in the stomach
- SSRIs and St John's Wort – used for the treatment of depression
- Tramadol – a pain killer
- Triptans – used for the treatment of migraines.

**HOW PETHIDINE FRESENIUS SHOULD BE USED**

Being an injectable, PETHIDINE FRESENIUS would normally be administered by your doctor or healthcare provider. It is unlikely that you would administer PETHIDINE FRESENIUS to yourself.

Your doctor will decide what your dose is and for how long you will receive PETHIDINE FRESENIUS. This will vary from patient to patient. It will depend on your condition and other factors, such as your physical condition, weight, age, as well as other medicines that you are taking at the time or after.

For the relief of pain, PETHIDINE FRESENIUS is usually given in divided doses throughout the day.

PETHIDINE FRESENIUS injection is administered either:

- directly into the muscle (intramuscular)
- beneath the skin (subcutaneous)
- or directly into the vein (intravenous).

**Do not share medicine prescribed for you with others.**

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

Since a healthcare professional will administer PETHIDINE FRESENIUS, he/she will control the dosage. However, in the event of an overdosage your doctor will manage the overdosage.

In the unlikely event of an overdose, you may experience any of the following symptoms:

- Muscle twitching and tremors
- Dilated pupils
- Convulsions.

## 5. POSSIBLE SIDE EFFECTS

PETHIDINE FRESENIUS can have side effects.

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

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

- Allergic reaction. The symptoms may include:
    - Severe rash
    - Shortness of breath, tightness in the chest or wheezing
    - Swollen face
- Headache (associated with high blood pressure)
- Changes in your heart rate
- Dizziness and light-headedness (associated with low blood pressure).

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

- Sweating, flushing of the face
- A drop in body temperature
- A build-up of pressure within your head, disorientation

- Nausea, vomiting, constipation, dry mouth
- Restlessness, hallucinations, confusion, mood changes
- Difficulty in urinating
- Drowsiness
- Spinning sensation
- Changes in or loss of sexual drive
- Constriction of your pupil
- Stiffening of your muscles.

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

## 6. STORING AND DISPOSING OF PETHIDINE FRESENIUS

PETHIDINE FRESENIUS will be stored in the pharmacy or in the hospital wards. The injection is kept in a cool dry place at or below 30 °C.

Store all medicines out of reach of children.

## 7. PRESENTATION OF PETHIDINE FRESENIUS

**PETHIDINE HCl 25 mg/1 mL FRESENIUS** has a green ring above the neck of the ampoule.

**PETHIDINE HCl 50 mg/1 mL FRESENIUS** has an orange ring above the neck of the ampoule.

**PETHIDINE HCl 100 mg/2 mL FRESENIUS** has a black ring above the neck of the ampoule.

The 1 mL and 2 mL clear glass ampoules are available in packs of 10.

## 8. IDENTIFICATION OF PETHIDINE FRESENIUS

A sealed clear glass ampoule containing a clear solution.

## 9. REGISTRATION NUMBERS

**PETHIDINE HCl 25 mg/1 mL FRESENIUS:** B/2.9/928

**PETHIDINE HCl 50 mg/1 mL FRESENIUS:** B/2.9/925

**PETHIDINE HCl 100 mg/2 mL FRESENIUS:** B/2.9/1630

## 10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

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## 11. DATE OF PUBLICATION

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