

**PACKAGE LEAFLET: INFORMATION FOR THE USER PETHIDINE
HYDROCHLORIDE 50 MG/ML SOLUTION FOR INJECTION (injection)**

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Pethidine Hydrochloride Injection is and what it is used for
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1. WHAT PETHIDINE HYDROCHLORIDE INJECTION IS AND WHAT IT IS USED FOR

Medicines that relieve pain are called analgesics. Pethidine is a strong analgesic and it belongs to a group of medicines known as opioid analgesics.

Pethidine Hydrochloride Injection may be used as an analgesic to relieve moderate-to-severe pain. It may be used before, during, or after surgery to relieve pain and it may be used to relieve pain during labour.

2. BEFORE YOU ARE GIVEN PETHIDINE HYDROCHLORIDE INJECTION

You should not be given Pethidine Hydrochloride Injection

- if you have ever had an allergic reaction to pethidine hydrochloride or any of the other ingredients used in this product.
- if you have severe breathing problems
- if you are in a coma
- if you are taking medicines called monoamine oxidase inhibitors for depression or if you have taken them within the last 14 days.
- if you are taking selegiline (for treatment of Parkinson's disease).

Take special care with Pethidine Hydrochloride Injection

- if you are feeling drowsy or confused
- if you are feeling weak or run-down
- if you have had an underactive thyroid or adrenal gland
- if you suffer from kidney, liver or gall-bladder disease
- if you have an enlarged prostate gland or have a difficulty passing urine
- if you have palpitations or change in normal heartbeat
- if you have problems with your breathing or if you suffer from asthma, bronchitis, or emphysema
- if you are complaining of headache, vomiting or if you have had a recent head injury
- if you have been drinking alcohol recently
- if you are suffering from cancer or a sickle cell anaemia
- if you suffer from a condition in which the intestines (small and large intestines or bowels) become severely inflamed (red or swollen). The most common are Crohn's disease and ulcerative colitis
- if you have a tumour in your adrenal glands called pheochromocytoma

- if you suffer from fits or convulsions..

You should talk to your doctor if you think this could apply to you.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This applies to medicines used some time ago and ones you are due to receive. This is important because pethidine may interfere with other medicines, such as the following ones:

- drugs for gastrointestinal problems (for example, cimetidine), epilepsy or convulsions (for example phenytoin), Parkinson's disease (for example selegiline), or HIV infection (for example ritonavir)
- medicines for anxiety or for any psychiatric illness, sleeping tablets, or pain relievers, anticholinergic drugs (which are used to treat various disorders including tummy problems, weak bladder).

Taking Pethidine Hydrochloride Injection with food and drink

Do not drink alcohol when you are being given pethidine as its effects may be increased by alcohol.

Pregnancy and breast-feeding

Pethidine should not be given in pregnancy before the beginning of labour, unless considered essential by the doctor.

Pethidine may get into breast milk. If you are breast feeding you should ask your doctor or pharmacist for advice.

Driving and using machines

Do not drive or operate machinery, because pethidine causes drowsiness. The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in
 - the information provided with the medicine and
 - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

3. HOW TO USE PETHIDINE HYDROCHLORIDE INJECTION

Your doctor will decide when and how to treat you with Pethidine Hydrochloride Injection. It may be given into a muscle or into the tissue beneath the skin and it may also be given by slow injection into a vein.

Dosage for adults

A single dose of between 25 mg and 100 mg may be injected into a muscle or into the tissue beneath the skin. For injection into a vein, a single dose of between 25 mg to 50 mg may be given slowly. The single doses may be repeated every four hours if required.

Dosage for elderly

The initial dose should not exceed 25 mg because these patients are more sensitive to the effects of pethidine.

Dosage for children

The usual single dose is 0.5 mg/kg to 2 mg/kg of body weight by injection into a muscle. If required, this dose may be repeated allowing at least four hours between doses.

A doctor, nurse or pharmacist will prepare the Pethidine Hydrochloride Injection for you. A doctor or nurse will usually give you the injection. You would not usually have to give the injection to yourself.

If you use more Pethidine Hydrochloride Injection than you should

Too much of this medicine may cause breathing difficulties, cold clammy skin, feeling cold, muscle weakness, other unwanted effects and later convulsions and coma. If you think too much of this injection was given, tell your doctor immediately.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pethidine Hydrochloride Injection can cause side effects, although not everybody gets them. For example, if pethidine is given repeatedly, it may result in drug dependence, a condition in which the drug becomes habit forming. This means that if treatment with pethidine is suddenly stopped, unpleasant withdrawal symptoms will occur. The symptoms of withdrawal are enlargement of pupils, sweating, muscle and stomach cramps, feeling tense and anxious, feeling restless, feeling irritable, disturbed sleep or inability to sleep, anorexia, loss of weight, nausea, vomiting, diarrhoea, increases in heart rate, breathing rate, blood pressure and temperature. To reduce the risk of these symptoms occurring, the dosage of pethidine should be reduced gradually.

Repeated use of pethidine may also lead to drug tolerance, a condition in which the drug becomes less effective with continued use. This means that higher doses of pethidine (or another analgesic) may be needed to control the pain, should you require repeated doses of pethidine ask your doctor for advice about drug dependence and tolerance.

Pethidine causes drowsiness (see the note on driving or operating machines).

Other side effects of pethidine treatment include: breathing difficulties, low blood pressure, fits or convulsions, sedation, syncope (fainting), lightheadedness, dizziness, constipation, confusion, nausea, vomiting, mild feeling of elation, agitation, tremor, uncoordinated muscle movements, hallucinations, visual disturbances, sweating, weakness, dry mouth, difficulty in passing water, changes in heart rate, palpitations, narrowing of the pupil, flushing, , abdominal pain due to spasm in the tubes carrying bile in the body, headache, low body temperature, mood changes, decreased interest in sex and impotence, excitedness, itching, and skin rashes.

Pain may occur at the spot where the injection is given and the skin around it may become red and irritated.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE PETHIDINE HYDROCHLORIDE INJECTION

Keep this medicine out of the reach and sight of children.

Do not use Pethidine Hydrochloride Injection after the expiry date, which is stated on the ampoule and carton.

Do not store above 30°C.

Keep the ampoule in the outer carton in order to protect from light.

Pethidine Hydrochloride Injection is for single use only and should be used immediately after opening. Discard any unused solution.

6. FURTHER INFORMATION

What Pethidine Hydrochloride Injection contains

The active substance is pethidine hydrochloride.

The other ingredients are sodium hydroxide, hydrochloric acid and water for injections.

What Pethidine Hydrochloride Injection looks like and contents of the pack

Pethidine Hydrochloride Injection is a clear and colourless sterile solution in clear glass ampoules.

The ampoules are available in two sizes:

1 ml ampoule (containing 50 mg pethidine hydrochloride, the active ingredient)

2 ml ampoule (containing 100 mg pethidine hydrochloride, the active ingredient).

Pack size: Pethidine Hydrochloride Injection 1 ml and 2 ml ampoules come in packs of 10.

Marketing Authorisation Holder and Manufacturer

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