Pethidine Hydrochloride

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

1. What is pethidine and what is it used for?

Pethidine is a drug with powerful pain relieving properties. Pethidine is used for the relief of moderate to severe pain and is used for pain relief during labour. It may also be used to stop you from feeling pain before and during an operation and to provide continuous pain relief if needed.

2. Before you are given Pethidine Injection

You should not be given Pethidine Injection if:

- you are allergic to pethidine (hypersensitivity) to pethidine Hydrochloride or any of the other ingredients listed in section 6.
- you suffer from asthma, severe breathlessness or other breathing difficulties
- you are suffering from severe headaches or have suffered a headache that is associated with sickness or that is getting worse
- you suffer from alcoholism
- you suffer from a depressive disorder (fits) such as epilepsy
- you have any liver or kidney problems
- you have any blood disorders
- you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. The concurrent use of MAOIs (including moclobemide) is contraindicated as they may result in CNS excitation or depression.
- you have taken it according to the instructions given by your prescriber or in the information provided with the medicine
- you have taken or might take any other medicines including medicines obtained without a prescription.

Pethidine Injection must not be used with drugs used to treat severe depression, such as monoamine oxidase inhibitors (MAOIs), particularly within 2 weeks of their withdrawal. The use of these patient groups may experience increased or prolonged adverse effects of the product.

Pethidine should be used with caution in patients with shock, hypothyroidism, advanced cirrhosis of the liver or cirrhosis, severe respiratory failure, severe liver or kidney disease, idiopathic hypotension, or malignant hypertension. Pethidine should be used with caution in patients with diseases of the cardiovascular system.

3. How Pethidine will be given

The main route of administration is intramuscular injection. Pethidine may also be given by slow intravenous injection or as a premedication.

4. How to store Pethidine Injection

Keep this medicine in the container it came in, away from direct light.

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6. Contents of the pack and other information

Pethidine 50mg/ml & 100mg/2ml Solution for Injection

Twin pack 50mg/ml and 100mg/2ml Solution for Injection

Pethidine Injection can affect your ability to drive and operate machines.

Driving and using machines:

- You should not drive or operate machines while you are receiving this medicine as it may affect your ability to drive safely.
- You should not drive or operate machines if you are suffering from severe headaches or have suffered a headache that is associated with sickness or that is getting worse.
- You may suffer from depression and should therefore be avoided as it may result in CNS excitation or depression.
- You may suffer from asthma, severe breathlessness or other breathing difficulties.
- You should be advised to avoid driving or operating machines if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Pethidine should not be administered to patients receiving monoamine oxidase inhibitors (including moclobemide) and the monoamine oxidase inhibitors (selegiline and rasagiline) or within two weeks of their withdrawal.

Pethidine should not be used in patients with severe renal or liver impairment.

Use of pethidine should be avoided in patients with severe obstructive airways disease and where there is danger of CNS excitation or depression.

Use of pethidine should be avoided in patients with diabetic arterial insufficiency.

Use of pethidine should be avoided in patients with diabetic gangrene where there is danger of gangrene.

Use of pethidine should be avoided in patients with a history of drug addiction.

Use of pethidine should be avoided in patients with a history of alcoholism.

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The plasma levels of pethidine may be reduced in the presence of opioid antagonists. Plasma levels of meperidine may also be reduced in the presence of opioid antagonists.

Possible increased serotoninergic effects when pethidine is given with SSRI's.

- Pethidine is incompatible with barbiturate salts and with other drugs including aminophylline, heparin sodium, merthiolate sodium, morphine sulphate, tetracycline hydrochloride, cefoperazone sodium, phenytoin sodium, sulphadiazine sodium, sodium iodide, sulphafluanide dimethylamine. Incompatibility has also been observed between pethidine hydrochloride and acetylsalicylic acid.

Pharmacodynamics:

Pethidine is a synthetic opioid analgesic similar to morphine although less potent and shorter acting. Its analgesic effect causes the release of histamine from mast cells resulting in a fall in blood pressure.

Skin & subcutaneous tissue disorders:

- dry skin
- itching
- alopecia
- hair loss
- pruritus
- rash
- urticaria
- angioneurotic oedema
- erythema multiforme
- Stevens-Johnson syndrome
- epidermal necrolysis
- toxic epidermal necrolysis
- bullous dermatitis

If you feel unwell after being given this medicine, or are at all concerned you have been given too much, tell your doctor or nurse immediately.

4. Possible Side Effects

- like all medicines containing pethidine can cause side effects, although not everybody gets them.

Repeated use of pethidine can result in tolerance and addiction

If any of the following symptoms occur, contact your doctor or the nearest accident and emergency department immediately. There are symptoms of a serious allergic reaction. Not known (frequency cannot be estimated from the available data):

hives or hives
- urticaria
- angioneurotic oedema
- erythema multiforme
- Stevens-Johnson syndrome
- epidermal necrolysis
- toxic epidermal necrolysis
- bullous dermatitis

If you are given too much of Pethidine Injection:

- nausea
- vomiting
- dry mouth
- constipation
- indigestion
- restlessness
- drowsiness
- feeling weak
- hallucinations (seeing or hearing things that aren't real)
- cough
- cold symptoms
- feeling lightheaded
- feeling faint
- feeling dizzy
- pins and needles
- feeling cold
- feeling hot
- feeling clammy
- feeling faint on standing up from a seated position
- feeling short of breath
- wheezing
- difficulty in breathing
- eye closure (miosis), shaking, cold, clammy skin, drop in body temperature, slow heartbeat and low blood pressure.

This medicine will be given to you in hospital so it is unlikely you will receive too much. Your doctor has information on how to recognise and treat an overdose.

If you are given too much of Pethidine Injection:

5. How to Store Pethidine Injection

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

This leaflet was last revised in: June 2019

6. Contents of the pack and other information

What Pethidine Injection contains Active Ingredient: Pethidine Hydrochloride Shw's Other Ingredients: sodium hydroxide and water for injections.

What Pethidine Injection looks like and contains of the pack: Pethidine Injection is a sterile solution, supplied in clear glass ampoules. Each ampoule contains 1ml or 2ml of the solution.

Marketing Authorisation Holder: Martindale Pharma, Bampton Road, Harold Hill, Romford, RM3 8UG, United Kingdom

Manufacturers: Macartney Laboratories Limited, T/A Martindale Pharma, Bampton Road, Harold Hill, Romford, RM3 8UG, United Kingdom

Rotaxmedica GmbH Arzneimittelwerk Bunsenstraße 4 D-22946 Tintau Germany

Product Licence Number: PL 01833/6150

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