Pethidine Hydrochloride 50mg/ml Solution for 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.

The name of your medicine is Pethidine Hydrochloride 50mg/ml Solution for Injection but will be referred to as “Pethidine Injection” throughout the remainder of this leaflet.

1. What Pethidine Injection is and what it is used for

Pethidine Injection is a type of medicine called an opioid analgesic. The word opioid means a substance similar to opium, for instance strong pain relievers such as morphine or codeine. An analgesic is a medicine that can be used to relieve pain. Pethidine Injection is used to relieve moderate to severe pain. Including pain associated with childbirth, or during an anaesthetic or following an operation. As well as relieving pain, pethidine has other effects including a sedative (calming) effect.

2. Before you are given Pethidine Injection

You should not start this medicine if:

• you know that you are allergic to Pethidine Injection or one of the other ingredients in this product (listed at the end of this leaflet), or to other strong pain relievers, such as morphine
• you have any problems that affect your breathing including chronic bronchitis or asthma
• you are taking monoamine oxidase inhibitors (MAOIs) or have been taking them within the last two weeks. MAOIs (e.g. phenelzine or isocarboxazid) are medicines used to treat depression
• you have recently suffered a head injury, have any conditions associated with raised pressure in the brain or a tumour of the adrenal gland (pheochromocytoma).

Patients in a coma should not be given this medicine.

Tell your doctor before you are given this medicine if you are pregnant, think you may be pregnant or are planning to become pregnant, or are breast-feeding. As with all pain relievers, pethidine may harm an unborn baby. As well as relieving pain, pethidine has other effects including a sedative (calming) effect.

Speak to your doctor if one of these applies to you before you are given this medicine.

Take special care and tell your doctor if:

• you have an underactive thyroid gland (which may cause tiredness, intolerance to cold, constipation, and puffiness of the face) or underactive adrenal glands (Addison’s disease)
• you have a condition that makes you have fits, eg. epilepsy
• you have problems with your heart causing an increased heart rate
• you have a problem with your liver, kidneys or gall bladder
• you are in a collapsed state from loss of blood or fluid
• you are feeling weak and run-down
• you are complaining of headache and vomiting
• you suffer from sickle cell anaemia
• you are elderly and in a poor state of health
• you have an enlarged prostate gland causing difficulty passing water (men only)
• you have low blood pressure
• you have weak muscular movement
• you have diseases of the stomach or intestine
• you have lung problems
• you have been drinking alcohol within the previous 24 hours.

Although some of these may be obvious, speak to your doctor if any of these applies to you before you are given this medicine.

Taking other medicines:

Tell your doctor before you are given this medicine if you are taking or have recently taken other medicines, including medicines obtained without a prescription. A large number of drugs can interact with Pethidine Injection which can significantly alter their effects. These drugs include:

• medicines for depression (e.g. tricyclic antidepressants such as amitriptyline) and medicines for anxiety (e.g. benzodiazepines such as diazepam)
• medicines for schizophrenia or other serious mental illness, such as phenothiazines (which may be prescribed to treat some medicines including some for treating allergic disorders, nausea (feeling sick) and vomiting (being sick)
• sedatives, sleeping tablets or barbiturates (e.g. phenobarbitone for epilepsy)
• corticosteroids (e.g. for a tumour or lung problem, or for Parkinson’s disease, or for a “weak” Bladder or as an inhaler for a breathing problem)
• anticholinergic drugs (used for disorders of the gastrointestinal tract)
• monoamine oxidase inhibitors A and B (used to treat depression)
• duloxetin (used to treat depression)
• dom peridone and metoclopramide (used for disorders of the gastrointestinal tract)
• codeine (for heart burn or ulcers)
• losartan (used to treat hypertension)
• phenytoin (antiepileptic medicine)
• isoniazid (used to treat tuberculosis)

If you are already taking one of these medicines, speak to your doctor before you receive Pethidine Injection.

Giving Pethidine Injection with food and drink:

You must avoid drinking alcohol whilst being given Pethidine Injection as it may increase the risk of developing breathing problems and low blood pressure.

Pregnancy and breast-feeding:

Tell your doctor before you are given this medicine if you are pregnant, think you may be pregnant or are planning to become pregnant, or are breast-feeding. As with all drugs, Pethidine Injection should only be given in pregnancy if absolutely necessary. Pethidine Injection may cause breathing problems in newborns.
Driving and using machines: Pethidine Injection can cause drowsiness and clouding of consciousness which could interfere with your ability to use machines. Do not operate machinery whilst you are taking this medicine. When your Pethidine Injection treatment has stopped, ask your doctor when it will be safe for you to use machines.

The medicine can affect your ability to drive as it may make you sleepy or dizzy. do not drive while taking Pethidine Injection 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.

Tolerance and dependence: Pethidine Injection can become less effective with repeated use. This is called tolerance and it means that the dose may have to be increased for Pethidine Injection to remain effective. If Pethidine Injection is used repeatedly, it becomes habit-forming. This is called dependence and if Pethidine Injection treatment is suddenly stopped, unpleasant withdrawal symptoms may occur.

Important information about some of the ingredients of Pethidine Injection: This medicine contains less than 1mmol sodium (23mg) per dose, i.e. is essentially "sodium-free".

3. HOW PETHIDINE INJECTION IS GIVEN TO YOU

Pethidine Injection may be administered by injection into a muscle, or into the tissue just below the skin by slow injection into the vein.

Your doctor will choose the most suitable dose depending on your age and your particular condition.

Dosage for Adults: A single dose of between 25 and 100mg may be injected into a muscle or into the tissue just beneath the skin. For injection into a vein, a single dose usually should not exceed 25mg. Individual injections should usually be repeated more frequently than every 4 hours if required.

Dosage for Elderly Patients or for Patients in a Weakened Condition: The initial dose should not exceed 25mg, because elderly patients or those in a weakened condition are more sensitive to the unwanted effects of pethidine.

Dosage for Children: The usual single dose is 0.5 to 2.0mg per kilogram of body weight by injection into a muscle. If necessary, this dose may be repeated, allowing at least 4 hours between doses.

To ensure that the correct dose is given, use of a special syringe with fine markings is recommended for administration in children. Alternatively, the solution may be diluted in Water for Injections to make it easier to measure the dose accurately.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you think you have been given more Pethidine Injection than you should have or you think you have missed a dose of your Pethidine Injection or have stopped using it too early, please tell your doctor or pharmacist immediately.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pethidine Injection can sometimes cause side-effects, although not everyone gets them. These are more common when Pethidine is given into a vein. All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

The most serious side effects are difficulty breathing and low blood pressure. Other side effects may include:

• disturbances in eyesight
• weakness, headache, dizziness
• flush of the face, feeling faint or fainting
• itch, rash, wheels (raised, itchy areas of skin), pain, and redness over site of injection
• difficulty in passing water and swelling over the body especially on legs
• feeling restless or agitated
• trembling, uncoordinated movements
• dry mouth, constipation, abdominal pain
• also in elderly patients there is an increased risk of delirium (confusion, feeling speechless and hallucinations). 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.

5. HOW TO STORE PETHIDINE INJECTION

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

Do not use this medicine after the expiry date which is stated on the carton and ampoule label after 'Expiry Date'. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the ampoules in the outer carton in order to protect from light.

The product should not be used after the expiry date printed on the ampoule or carton.

If only part of the contents of an ampoule is used, the remaining solution should be discarded.

6. FURTHER INFORMATION

The active substance is pethidine hydrochloride. The other ingredients are sodium hydroxide or dilute hydrochloric acid in water for injections BP.

What Pethidine Injection looks like and contains of pack:

Pethidine Injection is a clear, colourless, sterile solution. Each 1ml of solution contains 50mg of pethidine hydrochloride.

The solution is presented in clear glass ampoules (bottles), containing either 1ml or 2ml. The ampoules are then packed in cardboard cartons with 10 ampoules per box.

Marketing authorisation holder: Merck Pharama International Ltd., 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer: B. Braun Melsungen AG, Mittelweg 2, 12357 Berlin, Germany.

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