

Package leaflet: Information for the patient

Pethidine Hydrochloride 50mg/ml Solution for Injection

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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.

What is in this leaflet

1. What Pethidine Injection is and what it is used for
2. What you need to know before you are given Pethidine Injection
3. How Pethidine Injection is given to you
4. Possible side effects
5. How to store Pethidine Injection
6. Contents of the pack and other information

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, before an operation and as a medicine given before administration of an anaesthetic.

2. What you need to know before you are given Pethidine Injection

You should not be given Pethidine Injection

- if you are allergic to pethidine hydrochloride or any of the other ingredients in this medicine (listed in section 6)
- if you have any problems that affect your breathing including chronic bronchitis or asthma, shallow breathing or other breathing difficulties
- if you are taking monoamine oxidase inhibitors (MAOIs) or have been taking them within the last two weeks. MAOIs (e.g. phenelzine, moclobemide, isocarboxazid selegiline and rasagiline) are medicines used to treat depression (see ‘Other medicines and Pethidine Injection’)
- if you are taking ritonavir used for treatment of HIV infection
- if you are suffering from severe headaches or have suffered a head injury
- if you suffer from alcoholism
- if you suffer from a convulsive disorder (fits) such as epilepsy
- if you have any severe liver or kidney problems

- if you are suffering from a condition known as delirium tremens, caused by withdrawal from alcohol
- if your heartbeat is faster than usual
- if you suffer from a tumour of the adrenal gland known as pheochromocytoma
- if you suffer from diabetes.

Patients in a coma should not be given this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before being given Pethidine Injection

- if you are in shock, the symptoms of which include sweating, a fast pulse and cold, clammy skin
- if you have an underactive thyroid gland (which may cause tiredness, intolerance to cold, constipation and puffiness of the face)
- if you have underactive adrenal glands or suffer from problems related to your adrenal gland (the organ responsible for stress levels), including adrenocortical insufficiency (a lack of the hormones produced by the adrenal gland)
- if you suffer from fits
- if you have problems with your heart causing an increased heart rate
- if you suffer from any problem with your bowel, liver, kidneys or gall bladder
- if you have any problems that affect your breathing
- if you suffer from low blood pressure due to loss of blood or fluid
- if you suffer from raised pressure in the brain
- if you were born with sickle cell anaemia, where you have abnormally shaped red blood cells
- if you are elderly and in a poor state of health
- if you have an enlarged prostate gland causing difficulty in passing water (men only)
- if you have cancer
- if you are dependent on alcohol
- if you have weak muscular movement
- if you have lung problems
- if you are taking any medicine from the group of medicines known as benzodiazepines. Taking these medicines with Pethidine may result in sedation, difficulties in breathing (respiratory depression), coma and may be fatal. Even if benzodiazepines are prescribed, your doctor may need to change the dose, the duration of treatment or monitor you regularly.

This product must be used with caution in newborn and premature babies. This product may cause difficulty in breathing (respiratory depression) in neonates and young infants.

If you are elderly or ill, or your baby or child is being given Pethidine Injection, special care will be taken.

If any of the above apply to you or your child, please tell your doctor before being given Pethidine Injection.

Other medicines and Pethidine Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pethidine Injection must not be used with drugs used to treat severe depression, such as rasagiline or moclobemide, or if you are within 2 weeks of discontinuing them. These drugs are known as Monoamine Oxidase Inhibitors (MAOI's).

A large number of drugs can interact with Pethidine Injection which can significantly alter their effects.

These drugs include:

- medicines to treat depression (e.g. tricyclic antidepressants such as amitriptyline)
- selegiline, a medicine used to treat Parkinson's disease
- ritonavir, a medicine used to treat HIV
- medicines for anxiety (anxiolytics) (e.g. benzodiazepines such as diazepam)
- medicines used to help you to sleep (hypnotics)
- medicines to treat schizophrenia or other serious mental illness, such as phenothiazines (which may be present in various medicines including some for treating allergic disorders)
- sedatives, sleeping tablets or barbiturates (e.g. phenobarbital for epilepsy)
- domperidone and metoclopramide (used for disorders of the gastrointestinal tract)
- pain relievers and other opioid medicines.

Other medicines which may interact with Pethidine Injection are:

- Cimetidine (for heart burn or stomach ulcer)
- anticholinergic drugs (e.g. for a stomach or intestine problem, for Parkinson's disease (a condition where you get tremor, stiffness and shuffling), for a "weak" bladder, or as an inhaler for a breathing problem, for example ipratropium bromide, oxybutynin, orphenadrine and hyoscine hydrobromide)
- Halothane, a gas used in general anaesthesia
- medicines for depression (eg. tricyclic antidepressants such as amitriptyline)
- monoamine oxidase inhibitors (MAOIs) (e.g. phenelzine or isocarboxazid used to treat depression)
- ciprofloxacin, an antibiotic used to treat a number of bacterial infections
- mexiletine, a medicine used to treat seriously irregular heartbeats
- concomitant use of Pethidine and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe Pethidine together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

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

Pethidine Injection with food, drink and alcohol

You must avoid drinking alcohol before or after being given Pethidine Injection.

Pregnancy and breast-feeding

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.

As with all drugs Pethidine Injection should only be given in pregnancy or when breast-feeding if absolutely necessary. Pethidine can pass into your baby either through your blood. It can be administered as pain relief during childbirth but it may cause breathing problems in newborns.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Pethidine Injection will cause drowsiness 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 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.

Tolerance dependance and withdrawal

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, like nausea, vomiting, loss of appetite and restlessness may occur.

Information on Sodium content

This medicine contains less than 1 mmol sodium (23mg) per dose, that is to say essentially 'sodium-free'.

3. How Pethidine Injection is given to you

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

You should be lying down when the injection is given. Your doctor will choose the most suitable dose depending on your age and your particular condition.

Elderly

Elderly patients may require reduced doses.

Use in children

In children the dose is calculated according to the child's weight.

If you think you have been given more Pethidine Injection than you should have

The symptoms and signs of taking too much of this medicine include shallow breathing, drowsiness, incoordination, coma, seizures, blue skin and lips, 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 feel unwell after being given this medicine, or are at all concerned you have been given too much, tell your doctor or nurse immediately.

This is unlikely as your injection will be administered by a doctor or nurse. If you are concerned about the dose, discuss this with your doctor.

If you think you have missed a dose of Pethidine Injection

Tell your doctor or nurse immediately.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Repeated use of pethidine can result in tolerance and addiction

All medicines can cause allergic reactions although serious allergic reactions are rare.

Any sudden wheeziness, tightness of the breast and difficulty in breathing, swelling of the eyelids, face or lips, skin rash (red spots), fever or itching (especially affecting your whole body) and collapse should be reported to a doctor immediately.

The following side effects have also been reported:

Very common: may affect more than 1 in 10 people

- feeling sick (nausea)
- being sick (vomiting)
- dry mouth
- constipation,
- lightheadedness, dizziness, sleepiness
- slowing of breathing or shallow breathing
- sweating
- flushing of the face
- itching, rash causing redness of the skin

- feeling faint on standing up from a seated
- fits
- trembling, uncoordinated muscle movements
- headache
- CNS excitation
- fainting
- low blood pressure, the symptoms of which include feeling dizzy or light-headed, feeling weak and fainting.
- high blood pressure
- dilatation of blood vessels (vasodilatation).

Not known: frequency cannot be estimated from the available data

- addiction
- confusion
- feeling of unease (anxiety)
- nervousness
- changes in mood
- disturbances in eyesight
- dry eye
- pin-point pupils
- delay in blinking reflex when things are close to your eye
- sensation of spinning (vertigo)
- spasms in the lower abdomen
- muscle twitching
- reduced sex drive
- difficulty achieving or maintaining an erection
- hypothermia, the symptoms of which include shivering, drowsiness and feeling weak
- weakness
- seeing or hearing things that are not there (hallucinations)
- feeling overly happy (euphoria) or overly sad (dysphoria)
- irregular heartbeats, fast or slow heartbeats, loss of consciousness,
- difficulty in passing urine
- feeling agitated
- inability to empty the bladder completely (urinary retention)
- abdominal pain caused by kidney stones (renal colic)
- pain or irritation at the site of injection or local tissue, wheal, redness over the vein (after an injection into the vein)

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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance

Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

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 'Exp'. The expiry date refers to the last day of that month.

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

Once the ampoule has been opened it should be used immediately. If only part of the contents of an ampoule is used, the remaining solution should be discarded.

Do not use the solution if the ampoule is damaged or if the contents are discoloured in any way or contains particles in it.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Pethidine Injection contains

- The active substance is Pethidine Hydrochloride. Each 1ml contains 50mg of Pethidine Hydrochloride (100mg in 2ml).
- The other ingredients are sodium hydroxide or dilute hydrochloric acid in water for injections.

What Pethidine Injection looks like and contents of pack

Pethidine Injection is a clear, colourless, sterile solution for injection in 1ml or 2ml clear glass ampoules.

Pack size: The ampoules are then packed in cardboard cartons with 10 ampoules per box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mercury Pharmaceuticals (Ireland) Ltd,
4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer

B Braun Melsungen AG, Mistelweg 2, 12357 Berlin, Germany.

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