

Pethidine 50mg Tablets

Pethidine Hydrochloride

Read all of this leaflet carefully before you take 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.
- This medicine has been prescribed for you personally and you must not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- 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.

What is in this leaflet:

1. What Pethidine Tablets are and what they are used for
2. Before you take Pethidine Tablets
3. How to take Pethidine Tablets
4. Possible side effects
5. How to store Pethidine Tablets
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1. What Pethidine Tablets are and what they are used for

Pethidine is an opioid analgesic with pain relieving properties. This medicine is used for the relief of moderate to severe pain including pain during labour and before and during operations.

2. Before you take Pethidine Tablets

You should not take Pethidine Tablets if:

- you are allergic to Pethidine or any of the ingredients of this medicine (listed in section 6)
- you suffer from asthma, shallow breathing and other breathing difficulties
- you are taking or have taken within the last two weeks a type of drug used to treat severe depression known as monoamine oxidase inhibitors (MAOIs) (see 'Taking other medicines')
- you suffer from alcoholism
- you are suffering from severe headaches or have suffered a recent head injury (raised intracranial pressure)
- you have a tumour of the adrenal gland known as pheochromocytoma
- you suffer from a convulsive disorder (fits) such as epilepsy
- you suffer from a problem that could cause paralysis of the small intestine (paralytic ileus)
- your kidneys or liver are not working properly
- you are suffering from a condition known as delirium tremens, caused by withdrawal from alcohol
- you suffer from diabetes

Pethidine Tablets should not be given to you if you are unconscious.

Warnings and precautions

Talk to your doctor or pharmacist before being given Pethidine Tablets if

- your gall bladder is not working properly
- you have an underactive thyroid gland
- you think you may be in shock, as there is a risk of coma
- you have a rapid heartbeat
- you suffer from problems related to your adrenal gland (the organ responsible for stress levels), including Addison's disease (an illness caused by a lack of the hormone cortisol which controls stress levels)
- you have any prostate problems
- you suffer from problems with your bowel
- you suffer from a muscle disorder known as myasthenia gravis
- you suffer from an irregular heartbeat
- you have been told you suffer from a severe heart problem known as cor pulmonale
- you suffer from low blood pressure
- you suffer from shallow breathing
- you are taking Selegiline, a medicine used to treat Parkinson's disease, or Ritonavir, a medicine used to treat HIV and AIDS.

If you are elderly or ill you should take special care when taking Pethidine Tablets.

Tolerance and dependence

After prolonged use of Pethidine Tablets it is possible to develop tolerance and dependence on the medicine. If you feel that Pethidine Tablets are no longer providing adequate pain relief you should talk to your doctor.

Other medicines and Pethidine Tablets

Tell your doctor, nurse or midwife if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription.

Pethidine Tablets **must not** be used with drugs used to treat severe depression, such as phenelzine or moclobemide, or if you are within 2 weeks of discontinuing them. These drugs are known as Monoamine Oxidase Inhibitors (MAOIs).

Other medicines which may interact with Pethidine Tablets are:

- medicines for sleeping problems (sedatives) and anxiety, such as chloral, diazepam, and barbiturates
- CNS depressants (drugs that act on the brain and make you feel drowsy or faint). These include sleeping pills, anti-histamines (medicines used to treat allergies) that make you drowsy, medicines used to treat certain mental disorders, other pain killers or a general anaesthetic.
- anaesthetics
- mood stabilisers (drugs used to treat mental disorders) e.g. chlorpromazine
- mexiletine, a drug used to treat an irregular heartbeat
- cimetidine, a drug used to treat stomach ulcers
- anticonvulsants (drugs used to stop fits), such as phenytoin.
- medicines used to treat feeling or being sick such as domperidone and metoclopramide
- cisapride, a drug used to treat gastric reflux
- alcohol
- antibiotics (medicines used to treat bacterial infections), such as ciprofloxacin
- duloxetine, a medicine used to treat depression
- medicines used to treat depression known as SSRIs, such as citalopram or paroxetine
- medicines used to treat depression known as tricyclic antidepressants, such as amitriptyline or clomipramine
- medicines used to treat anxiety known as anxiolytics, such as diazepam or lorazepam
- carbamazepine, a medicine used to treat epilepsy (fits) and bipolar disorder.

Concomitant use of Pethidine Tablets 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 where 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.

Pregnancy, breast-feeding and fertility

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 Tablets should not be taken in the first three months of pregnancy unless your doctor considers their use to be essential.

Pethidine can pass into your baby either through your blood (during pregnancy and labour) or through your breast milk. This can cause breathing problems in newborn babies. Your doctor will be aware of this and will correct the problem and discuss feeding with you.

Driving and using machines

This medicine can affect your ability to drive and operate machinery. Do not drive or operate machinery if you feel drowsy or cannot think clearly.

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.

Taking Pethidine Tablets with food, drink and alcohol

You are advised not to drink alcohol during your treatment with Pethidine Tablets.

Pethidine Tablets contain lactose and sucrose If you have been told by your doctor that you have an intolerance to some sugars (lactose, sucrose), contact your doctor before taking this medicinal product.

Continued overleaf

3. How to take Pethidine Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

This medicine is for oral use.

Adults:

1-3 tablets (50-150mg) as a single dose. This may be repeated if the doctor decides this is needed but it should not be repeated more often than every four hours.

Elderly and infirm patients:

1 tablet (50mg). This may be repeated if the doctor decides this is needed but it should not be repeated more often than every four hours. Your doctor may increase this to 2 or 3 tablets once your reaction to Pethidine is known.

Children:

A single dose of 0.5-2mg/kg body weight. This may be repeated if the doctor decides this is needed but it should not be repeated more often than every four hours.

If you forget to take Pethidine Tablets

If you have missed a dose take it as soon as you remember unless it is nearly time for your next dose. Then continue your normal dose times. Do not take a double dose.

If you have taken more Pethidine Tablets than you should

If you take too much of your medicine seek immediate medical advice from your doctor or your nearest hospital. Symptoms of an overdose include shaking, fits, and sudden or unexpected difficulty in breathing.

If you stop taking Pethidine Tablets

You should not stop taking Pethidine Tablets until advised to do so by your doctor. If you stop treatment too suddenly you may experience symptoms of withdrawal such as stomach pains, feeling sick and feeling anxious. Your doctor will advise you how to stop your treatment with Pethidine Tablets.

4. Possible side effects

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

Tolerance, addiction and withdrawal Repeated use of pethidine can result in tolerance and addiction. Prolonged use of this medicine can result in mental and physical dependence on pethidine which may result in withdrawal symptoms if your treatment is stopped too quickly. The withdrawal symptoms of Pethidine Tablets include sweating, anxiety, difficulty sleeping, loss of appetite, pain, stomach cramps and diarrhoea. If you are worried about this possible side effect please talk to your doctor.

If you have been given Pethidine Tablets during your pregnancy your baby may experience withdrawal symptoms shortly after birth.

These symptoms include restlessness, jerking or shaking, sweating, fever, unusually fast breathing, poor feeding and projectile vomiting. If you are concerned about the possible side effects this medicine may have on your unborn child please talk to your doctor before being given this medicine.

Serious side effects

If any of the following symptoms occur tell your doctor or nurse immediately. These are symptoms of a serious allergic reaction.

Not known (frequency cannot be estimated from the available data):

- sudden wheeziness and tightness of chest
- swelling of eyelids, face or lips
- skin lumps or hives
- skin rash (red spots), itchiness, fever
- collapse

Other side effects that may occur include:

Not known (frequency cannot be estimated from the available data):

- feeling of intense happiness (euphoria)
- feeling sick (nausea)
- being sick (vomiting)
- breathing difficulties
- restlessness
- changes in mood
- low mood
- drowsiness
- a feeling of dizziness or spinning
- constipation
- facial flushing
- dry mouth
- difficulty in passing urine
- an itchy rash or redness
- headache
- feeling very cold
- pin-point pupils
- delay in blinking reflex when things are close to your eye
- spasms in the lower abdomen
- reduced blood pressure, the symptoms of which include feeling dizzy or light-headed, feeling weak and fainting
- a slow, rapid or irregular heartbeat
- sweating
- difficulty achieving or maintaining an erection
- loss of sexual appetite
- hallucinations (seeing or hearing things that aren't real)
- muscle stiffness

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pethidine Tablets

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

Do not use this product after the expiry date which is on the carton and blister pack. The expiry date refers to the last day of that month.

Store in the original packaging. Do not store above 25°C.

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 to protect the environment.

6. Contents of the pack and other information

What Pethidine Tablets contain:

Active substance: Pethidine Hydrochloride 50mg per tablet.

Other ingredients: starch, lactose, sucrose, talc, magnesium stearate and acacia.

What Pethidine Tablets look like and contents of the pack:

The tablets are white, round and flat with bevelled edges. They have M50 marked on one face and a break line on the other. They are supplied in cartons of 5 blister packs each containing 10 tablets.

Marketing Authorisation Holder:

Martindale Pharma
Bampton Road
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Romford Essex
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Manufacturer:

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