

# PETHIDINE HYDROCHLORIDE 50 MG TABLETS

Pethidine hydrochloride

## Patient Information Leaflet



**Read all of this leaflet carefully before you start taking 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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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.

This medicine contains pethidine hydrochloride which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

### What is in this leaflet:

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

#### 1. What Pethidine hydrochloride is and what it is used for

Pethidine Hydrochloride is an opioid analgesic with pain relieving properties. This medicine has been prescribed for you for the relief of moderate to severe pain including pain during labour and before and during operations. It contains Pethidine hydrochloride which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

#### 2. What you need to know before you take Pethidine hydrochloride Tablets

**Do not take Pethidine hydrochloride tablets and tell your doctor if:**

- you are allergic (hypersensitive) to pethidine hydrochloride or any of the other ingredients in 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 (MAOI's) (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 phaeochromocytoma
- 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 Hydrochloride Tablets should not be given to you if you are unconscious.

### Warnings and precautions

**Tell your doctor before taking Pethidine Hydrochloride if:**

- your gall bladder is not working properly
- you have an underactive thyroid gland
- you think you may be in shock as there is 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

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

If 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 not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

### Tolerance and dependence

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

Talk to your prescriber before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Pethidine Hydrochloride tablets to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are

becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

### Other medicines and Pethidine Hydrochloride

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pethidine Hydrochloride 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 (MAOI's).

Other medicines which may interact with Pethidine Hydrochloride 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, antihistamines (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
- mexilitine, 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
- coumarins
- digoxin

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.

Co-administration is not recommended with

- serotonergic drugs, including selective serotonin reuptake inhibitors (SSRIs, such as paroxetine, fluoxetine, citalopram, escitalopram, sertraline, fluvoxamine), serotonin-noradrenaline reuptake inhibitors (SNRIs, such as venlafaxine, duloxetine), and medicinal products containing St John's wort (Hypericum perforatum), as an interaction cannot be excluded.

If you are unsure of the types of medicines you are taking, ask your doctor or pharmacist.

**Pregnancy and breast feeding**

If you are pregnant, think you may be pregnant or you are breastfeeding, you should consult your doctor before using the tablets.

Pethidine Hydrochloride Tablets should not be used in the first three months of pregnancy unless your doctor considers its use to be essential.

Pethidine hydrochloride 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

**Taking Pethidine hydrochloride Tablets with food and drink**

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

**Important information about some of the ingredients of Pethidine hydrochloride**

This product contains lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

**3. How to take Pethidine hydrochloride Tablets**

Your prescriber should have discussed with you, how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. This medicine is for oral use.

**Adults:**

- 1 - 3 tablets (50 - 150 mg) 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 (50 mg). 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 hydrochloride 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 take more Pethidine hydrochloride 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 hydrochloride Tablets:**

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

**Pregnancy**

Do not take Pethidine Hydrochloride tablets if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Pethidine Hydrochloride tablets during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Pethidine Hydrochloride tablets while you are breastfeeding as pethidine hydrochloride passes into breast milk and will affect your baby.

**If you forget to take Pethidine hydrochloride:**

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 to make up for a forgotten dose.

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

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, particularly when you first start taking it, although not everybody gets them.

Please tell your doctor or pharmacist if you notice any of the following effects or any effects not listed.

**Tolerance, addiction and withdrawal**

Unknown frequency: dependence and addiction (see section "How do I know if I am addicted?").

**Drug Withdrawal**

When you stop taking Pethidine Hydrochloride tablets, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood

pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

**How do I know if I am addicted?**

If you notice any of the following signs whilst taking Pethidine Hydrochloride tablets, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber

If you have been given Pethidine Hydrochloride 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.

- 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:**

- 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
- fainting
- feeling weak
- feeling faint on standing up from a seated position
- 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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (Tel: Freephone 0800 100 3352 or Website: [www.mhra.gov.uk/yellowcard](http://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 hydrochloride Tablets**

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

There are no special storage conditions for this medicinal product.

Do not use this medicine after the expiry date which is stated on the carton and blister as [EXP MM/YYYY]. The expiry date refers to the last day of that month.

Do not throw away any medicines 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 hydrochloride Tablets contain:**

The active substance (the ingredient that makes the tablets work) is pethidine hydrochloride. Each tablet contains 50 mg of the active ingredient.

The other ingredients are maize starch, lactose monohydrate, sucrose, talc, magnesium stearate and acacia.

**What Pethidine hydrochloride Tablets looks like and contents of the pack:**

Pethidine Hydrochloride 50 mg Tablets are white to off-white round tablets, diameter 8.0 mm, marked 'PE 50' on one side and a break line on the other.

Pethidine Hydrochloride tablets are available in boxes of 50 tablets.

**Marketing authorisation holder:**

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**Manufacturer:**

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