PACKAGE LEAFLET: INFORMATION FOR THE USER

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

Pethidine Hydrochloride

Read all of this leaflet carefully before you are given 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, nurse or midwife.
- 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.

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What is in this leaflet

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

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

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

Pethidine is a drug with powerful pain relieving properties.

This medicine has been prescribed for you for 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.

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. Before you are given Pethidine Injection

You should not be given Pethidine Injection if:
- you are allergic (hypersensitive) to Pethidine Hydrochloride or to any of the ingredients of this medicine (listed in section 6)
- you suffer from asthma, shallow breathing or other breathing difficulties
- you are suffering from severe headaches or have suffered a head injury
- you suffer from alcoholism
- you suffer from a convulsive disorder (fits) such as epilepsy
- you have any liver or kidney problems
- you are suffering from a condition known as delirium tremens, caused by withdrawal from alcohol
- your heartbeat is faster than usual
- you suffer from a tumour of the adrenal gland known as phaeochromocytoma
- you suffer from diabetes
- you are taking or have recently taken any drugs used to treat depression known as Monoamine Oxidase Inhibitors (MAOI's) (see 'Taking other medicines)

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
- suffer from thyroid problems
- 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)
- suffer from low blood pressure
- suffer from problems with your prostate
- suffer from problems with your gallbladder
- suffer from problems with your bowel
- have weak muscular movement
- have lung problems
- 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 Injection 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.

Contact your doctor if you experience any of the following symptoms:
- You experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.
- Severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) or the biliary tract system.

Sleep-related breathing disorders
Pethidine Injection can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Tolerance, dependence, and addiction

This medicine contains pethidine, which is an opioid. It can cause dependence and/or addiction.

Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Pethidine Injection can also lead to dependence, abuse, and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Pethidine Injection if:
- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Pethidine Injection, it could be a sign that you have become dependent or addicted:
- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Pethidine Injection).

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. 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.

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, nurse or midwife if you are taking, have recently 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 rasagiline 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 Injection include:
- selegiline, a medicine used to treat Parkinson's disease
- ritonavir, a medicine used to treat HIV
- cimetidine, a medicine used to treat stomach ulcers
- medicines used to reduce anxiety (anxiolytics) (eg. benzodiazepines such as diazepam)
- medicines used to help you to sleep (hypnotics)
- 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.
- phenytoin, a medicine used to treat fits
- medicines used to treat serious mental disorders (phenothiazines)
- citalopram, a medicine used to treat depression
- medicines for depression (eg. tricyclic antidepressants such as amitriptyline)
- sedatives, sleeping tablets or barbiturates (eg. phenobarbitone for epilepsy)
- domperidone and metoclopramide (used for disorders of the gastrointestinal tract)
- pain relievers and other opioid medicines
- ciprofloxacin, an antibiotic used to treat a number of bacterial infections
- mexiletine, a medicine used to treat seriously irregular heartbeats

Talk to your doctor if you have taken or are taking the following:
- Gabapentin or pregabalin (medicines used to treat epilepsy, nerve pain or anxiety).
- Medicines to treat depression;
- Medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics);
- Medicines to treat psychiatric disorders (antipsychotics or neuroleptics);
- Muscle relaxants;
- Medicines to treat Parkinson's disease.

Concomitant use of Pethidine Injection 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.

Continued overleaf

If you are in any doubt please tell your doctor of any medication you are taking.

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 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.

This medicine can affect your ability to drive and operate machinery 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.

Having Pethidine Injection with food, drink and alcohol
You are advised not to drink alcohol during your treatment with this medicine.

3. How Pethidine Injection will be given

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Pethidine Injection, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also, If you stop taking Pethidine Injection).

Your doctor will give Pethidine Injection to you as an injection into a vein (intravenously), under the skin (subcutaneously) or into a muscle (intramuscularly).

Adults
For the relief of moderate to severe pain:
The usual initial dose is 25-100mg either into a muscle or under the skin, or 25-50mg if given into a vein. The dose is given at a minimum of four hourly intervals if needed.

For pain relief during labour:
The usual dose is 50-100mg either into a muscle or under the skin every 1-3 hours during labour up to a maximum of 400mg in 24 hours.

For pain relief before and during an operation:
The usual dose is 50-100mg into a muscle one hour before the operation.

For continuous pain relief:
The usual dose is 10-25mg by slow injection into the vein as needed.

The elderly and ill
It is recommended that a reduced dose be used. The usual initial dose is up to a maximum of 25mg.

Children
For the relief of moderate to severe pain:
The usual dose is 0.5-2mg per kilogram of body weight by intramuscular injection.

For pain relief before and during an operation:
The usual dose is 1-2mg per kilogram of body weight into the muscle one hour before the operation.

If you are given too much of Pethidine Injection:
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.

If you stop taking Pethidine Injection
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.

Pethidine Injection should be used for the shortest duration necessary to relieve symptoms. If no effective pain relief is achieved while taking the medicine, you should seek the advice of a physician.

Pregnancy
Do not take Pethidine Injection 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 Injection during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

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

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

If any of the following symptoms occur, contact your doctor or nearest accident and emergency department **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):
- restlessness
- drowsiness
- constipation
- dry mouth
- feeling sick (nausea)
- being sick (vomiting)
- facial flushing
- sweating
- a fast or slow heartbeat
- palpitations (an irregular heart rhythm or missed beats)
- low blood pressure, the symptoms of which include feeling dizzy or light-headed, feeling weak and fainting.
- high blood pressure
- pin-point pupils
- a feeling of dizziness or spinning
- fainting
- feeling weak
- hallucinations (seeing or hearing things that aren't real)
- mood changes (symptoms include feeling tense and restless)
- headache
- feeling faint on standing up from a seated position
- slowed breathing
- a red, itchy rash
- reduced sex drive
- difficulty achieving or maintaining an erection
- pain, redness or itching at the injection site
- hypothermia, the symptoms of which include shivering, drowsiness and feeling weak
- feeling of intense happiness (euphoria)
- difficulty in passing urine
- spasms in the lower abdomen
- addiction
- confusion
- tremor or involuntary shaking
- convulsions
- dry eye
- dizziness
- muscle twitching
- drug dependence and addiction (see section "How do I know if I am addicted?").

You can become dependent on Pethidine Injection (for more information see section 2 Warnings and Precautions).

Drug Withdrawal
When you stop taking Pethidine Injection, 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 Injection, 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

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 Injection

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

You should not be given Pethidine Injection after the expiry date which is stated on the ampoule and carton label. The expiry date refers to the last day of that month. The doctor or nurse will check that the product has not passed this date.

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

6.Contents of the pack and other information

What Pethidine Injection contains
Active Ingredient: Pethidine Hydrochloride 5%w/v
Other Ingredients: sodium hydroxide and water for injections.

What Pethidine Injection looks like and contents 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:
Macarthys Laboratories Limited, T/A Martindale Pharma, Bampton Road, Harold Hill, Romford, RM3 8UG, United Kingdom.

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