

## **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

**This medicine contains pethidine 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 Injection is a type of medicine called an opioid analgesic.

It contains pethidine which belongs to a class of medicines called opioids, which are ‘pain relievers. An analgesic is a medicine that can be used to relieve pain. This medicine has been prescribed for you for relief of 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.

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 are given Pethidine Injection**

##### **You should not be given Pethidine Injection**

- if you are allergic to Pethidine Hydrochloride or any of the other ingredients of this medicine (listed in section 6), or to other strong pain relievers, such as morphine

- 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 (eg. moclobemide, phenelzine or 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 and isoniazid for tuberculosis
- if you are suffering from severe headaches or you have recently suffered a head injury,
- if you have any conditions associated with raised pressure in the brain or a tumour of the adrenal gland (pheochromocytoma).
- if you have any liver or kidney problems
- if you suffer from alcoholism
- if you suffer from a convulsive disorder (fits) such as epilepsy
- 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 diabetes.

Patients in a coma should not be given this medicine.

Speak to your doctor if one of these applies to you before you are 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 (Addison’s disease) 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 have a condition that makes you have fits, eg. epilepsy
- if you have problems with your heart causing an increased heart rate
- if you have a problem with your bowel, liver, kidneys or gall bladder
- if you are in a collapsed state from loss of blood or fluid
- if you are feeling weak and run-down
- if you are complaining of headache and vomiting
- if you suffer from sickle cell anaemia
- if you are elderly and in a poor state of health
- if you have an enlarged prostate gland causing difficulty passing water (men only)
- if you have low blood pressure
- if you have weak muscular movement
- if you have diseases of the stomach or intestine
- if you have lung problems
- if you have been drinking alcohol within the previous 24 hours.
- 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.

**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 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.

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.

If you are elderly or ill, or your baby or child is being given Pethidine Injection, special care will be taken. This medicine may cause difficulty in breathing (respiratory depression) in neonates and young infants.

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.

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

- medicines for depression (eg. tricyclic antidepressants such as amitriptyline) and medicines for anxiety (anxiolytics) (eg. benzodiazepines such as diazepam)
- medicines used to help you to sleep (hypnotics)
- medicines for schizophrenia or other serious mental illness, such as phenothiazines (which may be present in various medicines including some for treating allergic disorders, nausea (feeling sick) and vomiting (being sick))
- 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.
- sedatives, sleeping tablets or barbiturates (eg. phenobarbitone for epilepsy)
- cimetidine (for heart burn or stomach ulcers)
- duloxetine (used to treat depression)
- domperidone and metoclopramide (used for disorders of the gastrointestinal tract)
- monoamine oxidase inhibitor A and B (used to treat depression)
- ritanovir (antiviral), a medicine used to treat HIV
- pain relievers and other opioid medicines
- anticholinergic drugs (eg. for a tummy or intestine problem, or for a “weak” bladder or as an inhaler for a breathing problem)
- selegiline, a medicine used to treat Parkinson’s disease
- phenytoin, a medicine used to treat fits (antiepileptic medicine)
- isoniazid (used to treat tuberculosis)
- 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 receive Pethidine Injection.

### **Pethidine Injection with food, drink and alcohol**

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**

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.

#### **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. Pethidine Injection may cause breathing problems in newborns.

#### **Breast-feeding**

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

#### **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 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 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.

#### **Information on Sodium content**

This medicine contains less than 1mmol 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 just below the skin (subcutaneous) or by slow injection into the vein (intravenous).

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

**Adults:**

A single dose of between 25 - 100mg may be injected into a muscle or into the tissue just beneath the skin. For injection into a vein, a single dose of between 25 - 50mg may be given slowly. These single doses should not usually be repeated more frequently than every 4 hours if required.

**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.

**Use in 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**

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.

**If you think you have missed a dose of Pethidine Injection**

Tell your doctor, nurse immediately.

If you have any further questions on the use of this medicine, ask 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.

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, although not everyone gets them.

##### **Repeated use of pethidine can result in tolerance and addiction**

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

The most serious side effects are difficulty breathing and low blood pressure.

Other side effects that may occur include:

Uncommon: may affect up to 1 in 100 people:

- 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.

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

- disturbances in eyesight
- pin-point pupils
- dry eye
- delay in blinking reflex when things are close to your eye
- feeling sleepy
- weakness, headache,
- fits
- CNS excitation
- a feeling of dizziness or spinning
- fainting
- hallucinations (seeing or hearing things that are not there)
- dependence and addiction (see section “How do I know if I am addicted?”)
- confusion
- mood changes (symptoms include feeling tense and restless)
- flushing of the face
- itch, rash, wheals (raised, itchy area of skin),
- pain, and redness or itching over site of injection
- difficulty in passing urine and swelling over the body especially on legs
- feeling restless or agitated
- trembling, uncoordinated movements
- dry mouth, constipation, abdominal pain
- spasms in the lower abdomen

- also in elderly patients there is an increased risk of delirium (confusion, slurred speech and hallucinations).
- irregular heartbeats, fast or slow
- palpitations (an irregular heart rhythm or missed beats)
- lightheadedness
- feeling sick (nausea), being sick (vomiting), sweating
- rapid changes in the blood pressure
- feeling faint on standing up from a seated
- slowed breathing
- 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)
- increased or decreased body temperature
- overactive reflexes
- feeling overly happy (euphoria) or overly sad (dysphoria)
- anxiety, nervousness
- reduced sex drive
- difficulty achieving or maintaining an erection
- hypothermia, the symptoms of which include shivering, drowsiness and feeling weak
- muscle twitching.

### **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

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 or pharmacist. 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](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 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.

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. Contents of the pack and other information**

### **What Pethidine Injection contains**

- 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 contents 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:**

Mercury Pharmaceuticals Limited  
Dashwood House, 69 Old Broad Street,  
London, EC2M 1QS, United Kingdom

### **Manufacturer:**

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

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