

Professional Information Leaflet (PIL)

for Medicines for Human Use

Pethidine 50 mg and 100 mg Unimed

SCHEDULING STATUS S6

PETHIDINE 50 mg UNIMED (50 mg/1 ml Injection)

PETHIDINE 100 mg UNIMED (100 mg/2 ml Injection)

Pethidine Hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking PETHIDINE UNIMED

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PETHIDINE UNIMED has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1 WHAT PETHIDINE UNIMED is and what it is used for

Pethidine Unimed contains the active ingredient, Pethidine Hydrochloride which belongs to a group of medicines called opioid (narcotic) analgesics. It works by blocking the pain signals from reaching your brain is used for the relief of pain.

PETHIDINE UNIMED is used for the treatment of:

- Relief of pain.
- It is particularly useful for the control and relief of pain after you have had an operation.
- It may be used when you are in labour for the relief of labour pains.

2 What you need to know before you receive PETHIDINE UNIMED

PETHIDINE UNIMED should not be administered to you:

- if you are hypersensitive (allergic) to pethidine hydrochloride or to any of the ingredients of PETHIDINE UNIMED (listed in section 6),
- if you are suffering from breathing difficulties or if you are having an asthma attack.
- if you suffer from heart failure (when your muscles does not pump blood as well as it should) that resulted from lung disease.
- 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 suffer from a tumour of the adrenal gland known as phaeochromocytoma
- if you are taking medicines known as Monoamine Oxidase Inhibitors (MAOI's) (see 'Taking other medicines) or within 2 weeks of discontinuation of such treatment.
- if you are using antidepressants such as Selective Serotonin Reuptake Inhibitors (SSRIs) and St. John's wort or pain medication such as tramadol or triptans (used to treat severe headaches/migraines)
- if you are taking a medicine called ritonavir (used to treat HIV infections)

- if you are in a coma
- if you suffer from obstruction of the intestine due to paralysis of the intestinal muscles (paralytic ileus)
- if you suffer from an irregularly fast or erratic heartbeat (arrhythmia) that affects the heart's upper chambers (supraventricular tachycardia).

Warnings and precautions

Tell your doctor or health care professional before being given Pethidine Unimed:

- If you suffer from opioid addiction.
- If you are in shock (the symptoms of which include sweating, a fast pulse and cold, clammy skin).
- If you suffer from thyroid problems
- If you 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 low blood pressure
- If you are a male and suffer from problems with your prostate
- If you suffer from problems with your gallbladder
- If you suffer from problems with your bowel
- If you have weak muscular movement and rapid fatigue of muscles under voluntary control (myasthenia gravis)
- If you have lung problems
- if you have problems with your kidneys or liver
- if you are in labour
- if you are elderly or very ill
- if you or your family have a history of mental health disorders (difficulty in thinking,

understanding and judging clearly which causes loss of touch with reality), if you have depression, anxiety and suffer from alcohol and drug abuse.

Taking opioids or receiving opioids (as contained in Pethidine Unimed) over a long period of time produces:

- Tolerance (where you develop a requirement for increased doses of Pethidine Unimed to achieve the same pain-relieving effects).
- Dependence, such that when people stop taking/receiving opioids, they have physical and psychological symptoms of withdrawal (such as muscle cramping, diarrhoea, and anxiety).

Opioid addiction can cause life-threatening health problems, including the risk of overdose. Speak to your doctor if you experience any of these effects or if you are concerned.

Children and adolescents

Great care should be taken if Pethidine Unimed is given to newborns or babies, as they may be more sensitive to breathing difficulties associated with Pethidine Unimed use.

Other medicines and PETHIDINE UNIMED

Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines).

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

Tell your doctor if you are taking or have been given the following medicines as PETHIDINE UNIMED can affect how they work:

- Selegiline or rasagiline (medicine used to treat Parkinson's disease);
- ritonavir (medicine used to treat HIV);

- cimetidine (medicine used to treat stomach ulcers) and cyclizine (medicine used to treat nausea)
- anxiolytics (medicine used to reduce anxiety) eg. benzodiazepines such as diazepam;
- hypnotics (medicine used to help you to sleep);
- CNS depressants (medicine 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; alcohol;
- phenytoin (medicine used to treat fits);
- phenothiazines (medicines used to treat serious mental disorders);
- medicine for depression (eg. tricyclic antidepressants such as amitriptyline);
- phenobarbitone (medicines used to treat epilepsy sedatives, sleeping tablets or barbiturates);
- domperidone (medicines used to treat disorders of the gastrointestinal tract);
- pain relievers used to treat moderate to severe pain (such as tramadol) and other opioid medicines;
- ciprofloxacin (for antibiotic used to treat a number of bacterial infections);
- mexiletine (medicine used to treat seriously irregular heartbeats);
- Citalopram (SSRIS) and St John's Wort used for the treatment of depression;
- Triptans (medicines used for the treatment of migraines).

Concomitant use of Pethidine Unimed and sedative medicines such as benzodiazepines or related medicines 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 Unimed together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

PETHIDINE UNIMED with Alcohol

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking PETHIDINE UNIMED.

Driving and using machines

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

3. How to receive PETHIDINE UNIMED

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself PETHIDINE UNIMED. It will be given to you by a person who is qualified to do so.

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

Your doctor will tell you how long your treatment with PETHIDINE UNIMED will last. If you have the impression that the effect of PETHIDINE UNIMED is too strong or too weak, tell your doctor or pharmacist.

If you receive more PETHIDINE UNIMED than you should

Since a healthcare provider will administer PETHIDINE UNIMED, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

In the unlikely event of an overdose, you may experience any or the following symptoms:

- Muscle twitching and tremors.

- Dilated pupils.
- Convulsions.

If you forget to use PETHIDINE UNIMED

Since a health care provider will administer PETHIDINE UNIMED it is unlikely that the dose will be missed.

4. Possible side effects

PETHIDINE UNIMED can have side effects.

Not all side effects reported for PETHIDINE UNIMED are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving PETHIDINE UNIMED, please consult your health care provider for advice.

If any of the following happens, stop taking PETHIDINE UNIMED and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PETHIDINE UNIMED.

You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain, angina, changes in the way your heart beats, for example, if you notice it beating faster, difficulty breathing,
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you,

- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects with frequency unknown:

- addiction
- confusion
- mood changes (symptoms include feeling tense and restless)
- feeling of intense happiness (euphoria)
- hallucinations (seeing or hearing things that aren't real)
- dizziness
- drowsiness
- restlessness
- tremor or involuntary shaking
- convulsions
- feeling faint on standing up from a seated position
- headache
- fainting
- feeling weak
- a fast or slow heartbeat
- dry eye
- pin-point pupils, corneal reflex decreased
- a feeling of dizziness or spinning
- 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
- feeling sick (nausea)
- being sick (vomiting)
- constipation
- dry mouth
- facial flushing
- sweating
- slowed breathing
- spasms in the lower abdomen
- a red, itchy rash
- muscle twitching
- difficulty in passing urine
- reduced sex drive
- difficulty achieving or maintaining an erection
- hypothermia, the symptoms of which include shivering, drowsiness and feeling weak
- pain, redness or itching at the injection site

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

5. How to store PETHIDINE UNIMED

- Store at or below 25 °C. Protect from light.
- Store in the original package.
- Do not use after the expiry date stated on the pack.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Store all medicines out of reach of children.

6. Contents of the pack and other information

What PETHIDINE UNIMED contains

The active substance is Pethidine Hydrochloride

Each 1 ml of solution contains 50 mg of Pethidine Hydrochloride.

Each 2 ml of solution contains 100 mg of Pethidine Hydrochloride.

Other ingredients:

Nitrogen and water for injection.

What PETHIDINE UNIMED looks like and contents of the pack

PETHIDINE 50 mg UNIMED: Polystyrene containers with 10 x 1 ml ampoules.

PETHIDINE 100 mg UNIMED: Polystyrene containers with 10 x 2 ml ampoules.

Applicant: Unimed Healthcare (Pty) Ltd

Module 1.3.2.2

Product Name: Pethidine 50 mg Unimed (Injection)
Pethidine 100 mg Unimed (Injection)

Dosage form and strength: Each 1 ml solution contains Pethidine Hydrochloride 50 mg
Each 2 ml solution contains Pethidine Hydrochloride 100 mg

Holder of Certificate of Registration

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