

 PACKAGE LEAFLET:
Information for the patient

PETIDINE

Solution for injection – 100 mg / 2 ml
(Pethidine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Petidine is and what it is used for
2. Before you take Petidine
3. How to take Petidine
4. Possible side effects
5. How to store Petidine
6. Further information

1. WHAT PETIDINE IS AND WHAT IT IS USED FOR

Pethidine is a synthetic opioid analgesic that acts mainly as an opioid agonist of μ - receptors. Pethidine has the same action and use with morphine, but it is more lipid-soluble than morphine and has a less potent and shorter-lasting analgesic effect. Its analgesic effect lasts for 2 to 4 hours.

Pethidine is indicated in:

- the relief of pain in malignant tumors;
- severe neuritis;
- birth activity disorders (severe contractions associated with pain during dilatation over 3 cm);
- acute pulmonary edema;
- calming of spasms of smooth muscles of the digestive tract, biliary and urinary routes;
- premedication before general anesthesia;
- the relief of postoperative pain.

Your doctor may have given Petidine for a different purpose. Ask your doctor if you want to know why you have been given Petidine.

2. BEFORE YOU TAKE PETIDINE

Do not take Petidine if:

- you are hypersensitive to pethidine hydrochloride, to other similar drugs, or to any of the other excipients of the solution;
- the patient is in a comatose state;
- you have respiratory depression or disease with obstruction of the airways;
- you have increased intracranial pressure;
- you have head trauma;
- you have risk for paralytic ileus;
- you suffer from pheochromocytoma;
- you are being treated with monoamine-oxidase inhibitors (MAOIs) or if you have been treated with these medicines in the last 2 weeks;
- you suffer from convulsion disorders;
- you suffer from severe renal and hepatic impairment.

If you think you have any of the conditions mentioned above, consult your doctor first and follow the advice given.

Take special care with Petidine

- Pethidine should be used with special caution and at reduced doses in newborns and children, in the elderly and debilitated patients, in those with Myasthenia gravis, biliary tract disorders, hypothyroidism, hypotension, adrenocortical insufficiency, shock, prostate hypertrophy, supraventricular tachycardia, severe cor pulmonale, urethral stenosis, obstruction or inflammatory bowel disease.
- Care should be done with patients who are at the stage of chronic alcoholism. Do not use alcohol during treatment with pethidine because individual response can not be predicted.

- Pethidine depresses the respiratory center and therefore should be used with special care in patients with respiratory insufficiency and asthma (it must not be used during an acute asthma attack) and those with impaired respiratory function.
- Repeated use can cause tolerance, with a tendency to increase the dose in order to achieve the proper effect. It can cause physical and psychological dependence of the morphine type, with the appearance of withdrawal symptoms after abrupt discontinuation of treatment.
- Cross - tolerance can develop between narcotic analgesics.
- The accumulation of pethidine metabolites may lead to neurotoxicity.

It is not suitable for the treatment of chronic pain.

Taking other medicines

Inform your doctor or pharmacist if you are taking or have recently taken or you will take other medicines during treatment, even those without a prescription, because the drugs listed below may affect or be affected by pethidine:

- central nervous system depressants (tranquillizers, alcohol) because when combined with pethidine they may cause additive depression of this system;
- drugs used to treat depression like tricyclic antidepressants and serotonin reuptake inhibitors, because they increase the risk for toxicity and depression of the central nervous system;
- sedating antihistamines, because the sedative effects can be enhanced;
- drugs used to treat anxiety because they increase the risk for toxicity and depression of the central nervous system;
- drugs used to treat schizophrenia and other serious diseases of the central nervous system, phenothiazines because they provide a pronounced sedation and hypotension and prolongation of the respiratory depression;
- monoamine oxidase inhibitors must not be taken concomitantly with pethidine; pethidine should not be used if 2 weeks have not yet passed from the stopping of MAOIs because excitation or depression of the central nervous system may occur;
- rasagiline, selegiline, moclobemide must not be taken concomitantly with pethidine; pethidine should not be used if 2 weeks have not yet passed from the stopping of these drugs;
- analgesics and other opioid preparations,
- hydantoins (phenytoin, fosphenytoin) because they increase the hepatic metabolism of pethidine, reduce its effects, increase the risk for toxicity from norpethidine;
- ritonavir, because the concentration of pethidine decreases, the concentration of norpethidine and the toxicity from this metabolite increase;
- cimetidine (for the treatment of ulcer and gastric burning) because it increases the possibility of respiratory and central nervous system depression;
- nalmefene should not be used with pethidine;
- sodium oxybate, because pethidine enhances the effects of this drug, hence concomitant use should be avoided.

Seek the advice of a doctor or pharmacist if simultaneously with Petidine you also receive the above-mentioned drugs.

Taking Petidine with food and drinks

You should not use alcohol during treatment with pethidine because individual response can not be predicted. The sedative and hypotensive effect can be enhanced.

Pregnancy

Tell your doctor or pharmacist if you are pregnant or are planning to become pregnant and take his advice for the use of this drug during pregnancy. Pethidine passes the placenta and can cause respiratory depression and withdrawal symptoms in the child when used during pregnancy. The use of pethidine in pregnancy can be done only if absolutely necessary and under careful oversight.

Breast-feeding

Tell your doctor or pharmacist if you are breast-feeding your baby and take his advice for the use of this drug during this period. Pethidine is excreted in breast milk, therefore care should be taken if it is used during this period.

Driving and using machines

Pethidine may damage the patient's ability to drive or work with machinery.

3. HOW TO TAKE PETIDINE

Always take Petidine exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist. If you feel that the effects of Petidine are too strong or too weak, talk to your doctor or pharmacist.

- For the treatment of pain

Adults, by subcutaneous or intramuscular injection:
25 - 100 mg, may be repeated after 4 hours.

- By slow intravenous injection:

25 - 50 mg, may be repeated after 4 hours.

- Children, by intramuscular injection:

0.5 - 2 mg / kg / weight.

- Obstetric analgesia, by subcutaneous or intramuscular injection:

50 - 100 mg, which may be repeated 1 - 3 hours later if required; the maximal dose is 400 mg in 24 hours.

- Premedication before surgery, by intramuscular injection:
25 - 100 mg, 1 hour before surgery.

For elderly or debilitated persons, a dose reduction is recommended.

If you take more Petidine

This drug will be administered to you in a hospital, so there are not a lot of chances for the overdose to occur, however inform your doctor immediately if you think that you have taken a higher dose than it is supposed. High doses can cause: convulsions, breathing difficulties, tremor, hypothermia.

If you forget to take Petidine

This drug will be administered to you in a hospital, so there are not a lot of chances for the forgetfulness to occur, however a double dose (or higher) should not be taken to make up the missed dose.

If you stop the treatment with Petidine

The treatment should not be discontinued immediately or without first consulting the doctor. The dose should be reduced gradually to minimize the withdrawal symptoms. If you have further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

All medicines may cause side effects. Sometimes they are serious, most of the time not, although not everyone manifests them. Inform your doctor about the following side effects that may occur:

- respiratory system: respiratory depression which is among the most major concerns, depression of the coughing reflex, laryngospasms;
- central nervous system or psychiatric effects: physical and psychological dependence of the morphine type, dizziness, confusion, drowsiness, hallucinations, euphoria, dysphoria, mood disorders, sleep disorders, headache;
- gastrointestinal tract: nausea, vomiting, constipation, abdominal pain, biliary tract spasm, dry mouth;
- cardiovascular system: hypotension, orthostatic hypotension, tachycardia, bradycardia, flushing, palpitations;
- dermatological: rash, pruritus, urticaria, problems at the injection site (local irritation, pain, redness);
- genitourinary tract: urinary retention, ureteric spasms;
- other: sweating, oedema, serious allergic reaction (sudden wheezing and tightness of the chest, swelling of eyelids, face or lips, skin lumps or urticaria, rash, itchiness, fever, collapse), myosis, visual disorders, sexual disorders.

Repeated use can cause tolerance, with a tendency to increase the dose in order to achieve the proper effect. In case of overdose, tremor, convulsion, muscular rigidity may happen. Inform your doctor if any of the above-mentioned side effects disturbs you. If you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PETIDINE

Keep out of the reach and sight of children!
Do not use Petidine after the expiry date stated on the package.
Do not store above 25 °C!
Keep in the original packaging to protect it from light.

6. FURTHER INFORMATION

What Petidine - Solution for injection contains

The active substance is pethidine hydrochloride.


Each 2 ml ampoule contains 100 mg pethidine hydrochloride.



The other ingredients are: hydrochloric acid or sodium hydroxide for pH adjustment, water for injection.


Content of the pack

Box with 10 ampoules and box with 100 ampoules (hospital use).

Explanatory of the illustration icons on the packaging:

 Prescription only medicine.

 Content.  Warning.

 Solution for injection.

Marketing Authorisation (MAH) Holder and Manufacturer:

 **PROFARMA Sh.a.**
Rruga "Myslym Keta"
Tel.: 00355 4 23 89 602
Tirana - ALBANIA

This leaflet was last revised in July 2016.