

PETHIDINE JUNO INJECTION

Pethidine hydrochloride

Consumer Medicine Information

WARNINGS

Limitations of use

Because of the risks associated with the use of opioids, pethidine should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

Pethidine poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

Pethidine can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing), even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting pethidine, after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of benzodiazepines and other central nervous system (CNS) depressants, including alcohol

Using pethidine with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimize the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using pethidine.

What is in this leaflet

This leaflet answers some of the common questions people ask about Pethidine Juno. It does not contain all the information that is known about pethidine.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given pethidine against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What PETHIDINE is for

Pethidine is a powerful drug used to relieve pain and produce sleepiness.

It can be used for the short-term management of severe pain or it can be used before painful operations to reduce the pain that you feel. It can also be used during childbirth to ease the pain of contractions.

Pethidine belongs to a group of medicines called opioid (narcotic) analgesics.

Pethidine works by changing the pain messages that are sent to the brain.

Your doctor will have explained why you are being treated with pethidine and told you what dose you will be given.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use.

Ask your doctor if you want more information.

Pethidine can be addictive. The risk of addiction is increased in people with a history of substance abuse or mental illness. The risk also increases the longer the drug is used and with higher doses. However, it is also important to keep your pain under control. Your doctor can advise you on how to best manage this.

This medicine is only available with a doctor's prescription.

Before you are given PETHIDINE

When you must not be given it

This medicine must not be given to you if you have an allergy to pethidine or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to pethidine may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Pethidine Juno should not be given to you if you:

- have respiratory diseases such as severe emphysema, severe chronic bronchitis, kyphoscoliosis, acute asthma or chronic airway disease.
- are suffering from a head injury or brain tumour
- are suffering from a convulsive state such as status epilepticus or tetanus, or if you have eclampsia or pre-eclampsia
- have an irregular heart beat (arrhythmia)
- have diabetic acidosis
- are undergoing treatment with, or have finished treatment in the last two weeks with, monoamine oxidase (MAO) inhibitors eg selegiline, phenelzine, tranylcypromine, moclobemide
- have severe liver disease
- have blood-thinning problems, or are receiving treatment for this disorder (eg warfarin)
- are suffering from acute alcoholism.

Pethidine Juno should not be given to you after the expiry date (EXP) printed on the pack.

If this medicine is used after the expiry date has passed, it may not work as well.

Pethidine Juno should not be given to you if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start therapy with pethidine, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have any allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant. Your doctor or pharmacist will discuss the possible risks and benefits of being given pethidine during pregnancy.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed. Pethidine passes into breast milk and therefore there is a possibility that your baby may be affected. Your doctor or pharmacist will discuss the possible risks and benefits of being given pethidine during breastfeeding.

Tell your doctor or pharmacist if you have any medical conditions, especially the following:

- lung or breathing problems
- a history of alcohol or drug abuse
- a history of mental illness
- under-active thyroid (hypothyroidism) and/or adrenal gland (Addison's disease)
- adrenal gland tumour (phaeochromocytoma)
- a history of epilepsy, fits (seizures) or head injuries.
- glaucoma (increased pressure in the eye)
- heart problems
- severe liver or kidney impairment
- severe inflammatory bowel disease or biliary colic
- diabetes

If you have not told your doctor or pharmacist about any of the above, tell them before you are given Pethidine Juno.

Taking other medicines

You must tell your doctor if you are taking any other medicines, including medicines that you buy at the pharmacy, supermarket or health food shop.

Some medicines and pethidine may interfere with each other. These include:

- antidepressants or medicines for anxiety disorders, such as:
 - selective serotonin reuptake inhibitors (SSRIs) or
 - serotonin and norepinephrine reuptake inhibitors (SNRIs),
 - tricyclic antidepressants (TCAs)
 - monoamine oxidase inhibitors (MAOIs) ie moclobemide, phenelzine, tranylcypromine
- medicines used for migraines (triptans)
- medicines used to prevent or treat nausea and vomiting (5-HT₃ receptor antagonists)

- selegeline, a monoamine oxidase inhibitor used to treat Parkinson's disease
- alcohol
- warfarin, a medicine used to prevent blood clots
- phenytoin or phenobarbital, medicines used to control fits or seizures
- other medicines which may make you drowsy such as sleeping tablets, tablets to calm your nerves, muscle relaxants, medicines to treat mental disorders, other strong painkillers, some antihistamines, general anaesthetics
- amphetamines
- cimetidine, a medicine used to treat stomach ulcers and gastric reflux.

These medicines may be affected by pethidine, or may affect how well it works. You may need different amounts of your medicine, or you may need to take/use different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while you are receiving Pethidine Juno.

If you have not told your doctor about any of these things, tell them before you are given any pethidine.

How PETHIDINE is given

How much is given

Your doctor will decide what dose of pethidine you will receive. This depends on your condition and other factors, such as your age and weight.

How it is given

Pethidine Juno will be given to you by injection by your doctor or nurse.

The injection may be given into a vein, into a muscle or sometimes under the skin.

You should be generally be lying down when the injection is given, especially if it is given into a vein.

Overdose

The doctor or nurse giving you Pethidine Juno will be experienced in its use, so it is extremely unlikely that you will be given too much.

However, the first signs of overdosage is usually a marked slowing of your breathing. In some cases fits, severe drowsiness, severe weakness, slow heart beat or pale and cold skin can occur.

Pethidine doses should be carefully worked out, so problems with overdosage are unlikely. There is another drug, called naloxone, which can be used to reverse the effects of too much pethidine if needed.

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have received too much Pethidine Juno. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using it

Things you must not do

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given Pethidine Juno.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given Pethidine Juno.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are undergoing therapy with Pethidine Juno.

If you plan to become pregnant while you are undergoing therapy with pethidine, tell your doctor or pharmacist.

Talk to your doctor or pharmacist about these possibilities if you think they may bother you.

Things you must not do

Do not give Pethidine Juno to anyone else, even if they have the same condition as you. Do not use Pethidine Juno to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop using pethidine, or lower the dosage, without checking with your doctor or pharmacist.

If you have been using pethidine for more than two weeks, you may experience unpleasant feelings if you stop it suddenly. Your doctor will probably want you to gradually reduce the amount of pethidine you are using, before stopping it completely.

Do not drive or operate machinery while you are being given Pethidine Juno.

Pethidine may cause drowsiness and impair your coordination and ability to make decisions. Driving and operating dangerous machinery should not be contemplated until the day following the last dose of pethidine.

Do not drink alcohol while you are being given Pethidine Juno.

Do not take any other medicines, whether they are prescription or over-the-counter medicines, unless they have been approved or recommended by a doctor or pharmacist that knows you are being given pethidine.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with Pethidine Juno.

Pethidine helps most people suffering severe pain, but it may have unwanted side-effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. If you are over 65 years of age you may have an increased chance of getting side effects.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

After you have been given Pethidine Juno you will probably feel light-headed, dizzy, sleepy and you may feel quite strange, especially if you are not lying down.

Tell your doctor or nurse if you notice any of the following side effects and they worry you.

- pain or irritation at the injection site
- drowsiness

- dizziness, light headedness or unsteadiness
- disorientation
- mood changes or hallucinations
- sweating
- blurred vision
- dry mouth
- nausea (feeling sick) and/or vomiting
- constipation.

These are the more common side effects of pethidine. Mostly these are mild and short-lived.

If any of the following happen, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital:

- slow or troubled breathing
- severe drowsiness or weakness
- slow or rapid heart rate
- difficult in urinating
- itchy rash
- agitation
- muscle twitching, jerking or fits (seizures)
- loss of consciousness.

These may be serious side effects. You may need urgent medical attention or hospitalisation.

Some people may get other side effects after being given pethidine.

Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Storage

If you are storing Pethidine Juno at home, it should be kept in the original pack in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not leave it in the car on hot days.

Disposal

Make sure that you return to your doctor or pharmacist any injections that have passed the use by (expiry) date marked on the pack, or if you have any left over when your doctor says you no longer need to be given pethidine.

Product Description

Each Pethidine Juno ampoule contains pethidine hydrochloride 50mg/mL as the active ingredient in Water for Injection. Sodium hydroxide or hydrochloric acid may be used for pH adjustment.

In the USA pethidine is known as meperidine.

Pethidine Juno is available in a 2mL glass ampoule in packs of 5.

Manufacturer

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