

DBL™ Pethidine Hydrochloride Injection BP

Pethidine Hydrochloride

Consumer Medicine Information

WARNING

Limitations of use

DBL Pethidine Hydrochloride Injection BP 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

DBL Pethidine Hydrochloride Injection BP 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

DBL Pethidine Hydrochloride Injection BP 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 and 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 other medicines while using Pethidine

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 minimise 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 common questions about DBL Pethidine Hydrochloride Injection BP.

It does not contain all the available information.

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

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you being given DBL Pethidine Hydrochloride Injection BP against the benefits they expect it will have for you.

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

Keep this leaflet in a safe place.

You may need to read it again.

What DBL Pethidine Hydrochloride Injection BP is used for

In some overseas countries, pethidine is called meperidine.

Pethidine is a pain killer that belongs to a group of medicines called opioid analgesics.

Pethidine acts in the brain and the spinal cord.

Pethidine is most commonly used to relieve severe pain. It may also be used just before, or during, an operation, to help the anaesthetic work better.

Your doctor may have prescribed pethidine for another reason.

Ask your doctor if you have any questions about why pethidine has been prescribed for you.

Pethidine may produce physical dependency if used for a long time (ie more than two weeks). Physical dependency means you may experience unpleasant feelings if you stop pethidine suddenly.

However, it is also important to keep your pain under control. Your doctor can advise you on how to prevent and manage this.

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

Before you are given DBL Pethidine Hydrochloride Injection BP

When you must not be given it

DBL Pethidine Hydrochloride Injection BP should 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.

DBL Pethidine Hydrochloride Injection BP should not be given to you if:

- you are an asthmatic, have breathing problems or have severe disease relating to the lungs.
- you are suffering from a head injury or brain tumour
- you have an irregular heart beat (arrhythmia)
- you are undergoing treatment with, or have finished treatment in the last two weeks with, monoamine oxidase (MAO) inhibitors eg selegeline, phenelzine, tranylcypromine, moclobemide

- you have severe liver or kidney disease
- you have blood-thinning problems, or are receiving treatment for this disorder (eg warfarin)
- you are suffering from acute alcoholism.
- you have a blockage in the stomach and intestine (severe constipation) or have severe pain in the stomach with bloating, gut cramps and vomiting (paralytic ileus)

DBL Pethidine Hydrochloride Injection BP 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.

DBL Pethidine Hydrochloride Injection BP 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 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 you 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 will discuss the possible risks and benefits of you being given pethidine during breastfeeding.

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

- lung or breathing problems
- alcohol abuse
- gall bladder disease or gallstones
- under-active thyroid (hypothyroidism)
- adrenal gland tumour (phaeochromocytoma) and/or when the adrenal glands are not working properly (Addison's disease).
- diabetes
- epilepsy, convulsions fits or seizures.
- snoring or sleep apnoea (you temporarily stop breathing or have difficulty breathing while asleep)

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

Addiction

You can become addicted to pethidine even if you use it exactly as prescribed. Pethidine may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking pethidine. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking pethidine suddenly, so it is important to use it exactly as directed by your doctor.

Tolerance

Tolerance to pethidine may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you

stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

DBL Pethidine Hydrochloride Injection BP given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Taking other medicines

Tell your doctor or pharmacist if you are taking/using any other medicines, including any that you buy without a prescription from your 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 migraine (triptans)
- medicines used to prevent or treat nausea and vomiting (5-HT₃ receptor antagonists)
- selegiline, a monoamine oxidase inhibitor used to treat Parkinson's disease

- alcohol
- warfarin, a medicine used to prevent blood clots
- medicines which may reduce the effects of pethidine such as rifampin (anti-tuberculosis medication), carbamazepine and phenytoin, medicines used to control fits or seizures
- medicines which may increase the effect of pethidine such as macrolide antibiotics (e.g. erythromycin), azole-antifungal agents (e.g., ketoconazole) and protease inhibitors or medication for HIV (e.g. ritonavir).
- other medicines which may make you drowsy such as sleeping tablets (e.g. benzodiazepines, hypnotics), tablets to calm your nerves (e.g. sedatives), muscle relaxants, medicines to treat mental disorders, other opioid analgesics or strong painkillers, some antihistamines.

Your doctor will minimise 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.

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 have more information on medicines to be careful with or avoid while you are receiving DBL Pethidine Hydrochloride Injection BP.

How DBL Pethidine Hydrochloride Injection BP 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

Your doctor or nurse will usually give pethidine to you.

Pethidine can be given as:

- an injection into a muscle,
- a slow injection into a vein,
- an injection under the skin or
- by a method called patient-controlled analgesia; this method allows you, the patient, to control the amount of pethidine you wish to receive. On experiencing pain, you can press a button which allows a dose of pethidine to be administered to you. To prevent you receiving too much pethidine, there is a "lockout" period built into the pump which prevents continuous injection of pethidine.

Your doctor will decide the appropriate way for you to be given pethidine.

If you receive too much (overdose)

DBL Pethidine Hydrochloride Injection BP is only recommended to be given for a maximum of 24 to 36 hours, however some people may need to receive it for longer.

If you or someone else have received too much (overdose) of pethidine and experience one or more of the symptoms below, call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally been given pethidine that was prescribed for you.

If someone has an overdose they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Severe drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat

- Nausea or vomiting
- Convulsions or fits (twitching or jerking)
- Severe weakness
- Pale and cold skin.

If you think you or someone else may have been given too much pethidine, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are being given DBL Pethidine Hydrochloride Injection BP

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given DBL Pethidine Hydrochloride Injection BP.

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

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

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

Things you must not do

Do not give DBL Pethidine Hydrochloride Injection BP to anyone else, even if they have the same condition as you.

Do not use DBL Pethidine Hydrochloride Injection BP 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 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.

Things to be careful of

Be careful driving or operating machinery until you know how pethidine affects you.

Pethidine may cause drowsiness, and impairment of coordination, in some people. Do not drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy or feeling uncoordinated.

Do not drink alcohol, while you are undergoing treatment with pethidine, unless otherwise advised by your doctor or pharmacist, as drowsiness and coordination impairment may be worse.

As pethidine may cause nausea and vomiting, your doctor is likely to prescribe medicine for you to take/ receive before the pethidine, to stop you feeling sick. Tell your doctor, pharmacist or nurse if you have any concerns about this.

Pethidine may also cause constipation, so your doctor is likely to prescribe laxatives to prevent this happening. Tell your doctor, pharmacist or nurse if you have any concerns about this.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are undergoing therapy with pethidine.

Pethidine helps most people with 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 or pharmacist to answer any questions you may have.

If you get any side effects, do not stop pethidine without first talking to your doctor or pharmacist.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- drowsiness
- dizziness or unsteadiness
- lightheadness
- sweating or flushing
- nausea and/or vomiting
- constipation
- hallucinations
- pain and irritation at the injection site
- blurred vision
- dry mouth
- mood changes.

These are the more common side effects of DBL Pethidine Hydrochloride Injection BP. Mostly they are mild and short-lived.

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

- severe drowsiness
- slow or rapid heart beat
- difficulty in urinating
- slow or troubled breathing
- severe weakness
- agitation
- twitching
- jerking
- seizures (fits)
- unconsciousness.

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

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

You may not experience any of them.

After you are given DBL Pethidine Hydrochloride Injection BP

Storage

DBL Pethidine Hydrochloride Injection BP should be stored in a cool, dark place where the temperature stays below 25C. It should be kept out of reach of children.

Disposal

If your doctor or pharmacist tells you to stop using DBL Pethidine Hydrochloride Injection BP or the medicines have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

DBL Pethidine Hydrochloride Injection BP is supplied as a clear, colourless, sterile solution in ampoules.

Ingredients

Active ingredients:

- pethidine, as the hydrochloride salt

Other ingredients:

- water for injection
- sodium hydroxide

DBL Pethidine Hydrochloride Injection BP does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

DBL Pethidine Hydrochloride Injection BP is available in the following strengths:

- 50mg/1mL AUST R 107386
- 100mg/2mL AUST R 107387

Date of leaflet preparation:

May 2020.

TM = Trademark