

DBL™ Pethidine Hydrochloride Injection BP

Pethidine (PETH-E-DEEN)

Consumer Medicine Information

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 or have breathing problems
- 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.

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 breast-feeding.

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) and/or adrenal gland (Addison's disease)
- adrenal gland tumour (phaeochromocytoma)
- diabetes
- epilepsy, convulsions fits or seizures.

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.

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 which belong to the group of medicines called monoamine oxidase inhibitors. ie moclobemide, phenelzine, tranylcypromine
- selegiline, a monoamine oxidase inhibitor used to treat Parkinson's disease
- alcohol
- warfarin, a medicine used to prevent blood clots
- phenytoin, a medicine used to control fits or seizures
- other medicines which may make you drowsy such as sleeping tablets, tablets to calm your nerves, medicines to treat mental disorders, other strong painkillers and some antihistamines.

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 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.

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much DBL™ Pethidine Hydrochloride Injection BP. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you have received too much pethidine, you may have symptoms which include severe drowsiness, slow or troubled breathing, twitching, jerking, severe weakness, slow heart beat, pale and cold skin.

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 25°C. 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

Australian Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 064 330

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500 Collins Street
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Australia

New Zealand Sponsor:

Hospira NZ Limited
23 Haining Street

Te Aro

Wellington

New Zealand

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

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

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