

DBL™ Pethidine Hydrochloride Injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I being treated with DBL Pethidine Hydrochloride Injection?

DBL Pethidine Hydrochloride Injection contains the active ingredient pethidine hydrochloride. DBL Pethidine Hydrochloride Injection is a pain killer that belongs to a group of medicines called opioid analgesics. It 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.

For more information, see Section [1. Why am I being treated with DBL Pethidine Hydrochloride Injection?](#) in the full CMI.

2. What should I know before treatment with DBL Pethidine Hydrochloride Injection?

Do not use if you have ever had an allergic reaction to pethidine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before treatment with DBL Pethidine Hydrochloride Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Pethidine Hydrochloride Injection and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is DBL Pethidine Hydrochloride Injection 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.

More instructions can be found in Section [4. How is DBL Pethidine Hydrochloride Injection given?](#) in the full CMI.

5. What should I know during treatment with DBL Pethidine Hydrochloride Injection?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, dentist and pharmacist you visit that you are being given pethidine.● If you become pregnant while you are being treated with pethidine, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">● Do not stop using this medicine suddenly. If you have been using pethidine for more than two weeks, you may experience unpleasant feelings if you stop pethidine suddenly.
Driving or using machines	<ul style="list-style-type: none">● Do not drive a car, operate machinery, or do anything else that could be dangerous until you know how pethidine affects you. Pethidine may cause drowsiness and impair coordination.

Drinking alcohol	<ul style="list-style-type: none"> Do not drink alcohol while you are being treated with pethidine.
Looking after your medicine	<ul style="list-style-type: none"> If you are being given DBL Pethidine Hydrochloride Injection while in hospital, it will be stored in the pharmacy or on the ward. Store below 25°C.

For more information, see Section [5. What should I know during treatment with DBL Pethidine Hydrochloride Injection?](#) in the full CMI.

6. Are there any side effects?

Common side effects are mild and usually short lived. These include drowsiness, dizziness or unsteadiness, light-headedness, sweating or flushing, nausea or vomiting, constipation, hallucinations, pain and irritation at the injection site, blurred vision, dry mouth and mood changes. If you experience serious side effects such as severe drowsiness, slow or rapid heart beat, difficulty in urinating, slow or troubled breathing, severe weakness, agitation, twitching, jerking, seizures (fits), or unconsciousness, you may need urgent medical attention or hospitalisation.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING:

Limitations of use

DBL Pethidine Hydrochloride Injection 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 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 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.

DBL™ Pethidine Hydrochloride Injection

Active ingredient(s): *pethidine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Pethidine Hydrochloride Injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DBL Pethidine Hydrochloride Injection.**

Where to find information in this leaflet:

- [1. Why am I being treated with DBL Pethidine Hydrochloride Injection?](#)
- [2. What should I know before treatment with DBL Pethidine Hydrochloride Injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is DBL Pethidine Hydrochloride Injection given?](#)
- [5. What should I know during treatment with DBL Pethidine Hydrochloride Injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being treated with DBL Pethidine Hydrochloride Injection?

DBL Pethidine Hydrochloride Injection contains the active ingredient pethidine hydrochloride.

DBL Pethidine Hydrochloride Injection is a pain killer that belongs to a group of medicines called opioid analgesics. Pethidine acts in the brain and the spinal cord.

DBL Pethidine Hydrochloride Injection 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.

2. What should I know before treatment with DBL Pethidine Hydrochloride Injection?

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

Warnings

Do not use DBL Pethidine Hydrochloride Injection if you:

- are allergic to pethidine, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction 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

Always check the ingredients to make sure you can use this medicine.

- are an asthmatic, have breathing problems or have severe disease relating to the lungs
- are suffering from a head injury or brain tumour
- have an irregular heart beat (arrhythmia)
- are undergoing treatment with, or have finished treatment in the last two weeks with, monoamine oxidase (MAO) inhibitors (e.g. selegiline, phenelzine, tranylcypromine, moclobemide)
- have severe liver or kidney disease
- have blood-thinning problems, or are receiving treatment for this disorder (e.g. warfarin)
- are suffering from acute alcoholism
- 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).

Check with your doctor if you:

- have or have had any other 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)
 - low or high blood sugar, diabetes
 - epilepsy, convulsions, fits or seizures
 - snoring or sleep apnoea (you temporarily stop breathing or have difficulty breathing while asleep)
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of you being given pethidine during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. 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.

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 using pethidine. Using it for a long time (i.e. more than two weeks) may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop using pethidine suddenly, so it is important to use it exactly as directed by your doctor.

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

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 using your medicine for as long as your doctor tells you. If you stop using 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 given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with DBL Pethidine Hydrochloride Injection and affect how it works. These include:

- antidepressants or medicines for anxiety disorders, such as:
 - selective serotonin reuptake inhibitors (SSRIs)
 - serotonin and norepinephrine reuptake inhibitors (SNRIs)
 - tricyclic antidepressants (TCAs)
 - monoamine oxidase inhibitors (MAOIs) e.g. moclobemide, phenelzine, tranylcypromine
- medicines used for migraines (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
- warfarin, a medicine used to prevent blood clots
- 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.

Medicines that may increase the effect of DBL Pethidine Hydrochloride Injection include:

- macrolide antibiotics (e.g. erythromycin)
- azole-antifungal agents (e.g. ketoconazole)
- protease inhibitors or medication for HIV (e.g. ritonavir).

Medicines that may reduce the effect of DBL Pethidine Hydrochloride Injection include:

- rifampicin (anti-tuberculosis medication)
- carbamazepine and phenytoin (medicines used to control fits or seizures).

Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Pethidine Hydrochloride Injection.

4. How is DBL Pethidine Hydrochloride Injection 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 is it given

- Your doctor or nurse will usually give DBL Pethidine Hydrochloride Injection to you.
- DBL Pethidine Hydrochloride Injection 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 use too much (overdose)

DBL Pethidine Hydrochloride Injection 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 DBL Pethidine Hydrochloride Injection and experience one or more of the symptoms below, urgent medical attention is required. 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.

Symptoms of an overdose may include:

- 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.

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.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know during treatment with DBL Pethidine Hydrochloride Injection?

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.

Pethidine may also cause constipation, so your doctor is likely to prescribe laxatives to prevent this happening.

Things you should do

- Tell any doctors, dentists and pharmacists who are treating you that you are being given DBL Pethidine Hydrochloride Injection.
- If you are about to be started on any new medicine, tell your doctor, dentist and pharmacist that you are being given DBL Pethidine Hydrochloride Injection.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being treated with DBL Pethidine Hydrochloride Injection.

- If you become pregnant while you are being treated with pethidine, tell your doctor or pharmacist.
- Tell your doctor, pharmacist or nurse if you have any concerns about being given pethidine.

Things you should not do

- Do not give DBL Pethidine Hydrochloride Injection to anyone else, even if they have the same condition as you.
- Do not use DBL Pethidine Hydrochloride Injection to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop using DBL Pethidine Hydrochloride Injection or lower the dosage without checking with your doctor or pharmacist. If you have been using DBL Pethidine Hydrochloride Injection 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 prescribed or recommended by a doctor or pharmacist who knows you are being given pethidine.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Pethidine Hydrochloride Injection affects you.

DBL Pethidine Hydrochloride Injection 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

You must not drink alcohol while using pethidine. 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.

Looking after your medicine

If you are being given DBL Pethidine Hydrochloride Injection while in hospital, it will be stored in the pharmacy or on the ward.

DBL Pethidine Hydrochloride Injection should be stored in a cool dry place, protected from light, where the temperature stays below 25°C.

Do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Do not use this medicine after the expiry date.

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

Getting rid of any unwanted medicine

If your doctor tells you to stop using DBL Pethidine Hydrochloride Injection or the expiry date has passed, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

If you are over 65 years of age you may have an increased chance of getting side effects.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

Common side effects

Common side effects	What to do
<ul style="list-style-type: none">● drowsiness● dizziness or unsteadiness● light-headedness● sweating or flushing● nausea and/or vomiting● constipation● hallucinations● pain and irritation at the injection site● blurred vision● dry mouth● mood changes	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p> <p>Mostly they are mild and short lived.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">● severe drowsiness● slow or rapid heart beat● difficulty in urinating● slow or troubled breathing● severe weakness	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● agitation ● twitching ● jerking ● seizures (fits) ● unconsciousness 	<p>You may need urgent medical attention or hospitalisation.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop treatment with any of your medicines.

7. Product details

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

What DBL Pethidine Hydrochloride Injection contains

Active ingredient (main ingredient)	Pethidine hydrochloride
Other ingredients (inactive ingredients)	Sodium hydroxide Water for injections

Do not use this medicine if you are allergic to any of these ingredients.

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

What DBL Pethidine Hydrochloride Injection looks like

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

It is available in the following strengths:

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

Who distributes DBL Pethidine Hydrochloride Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

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