

DBL™ Morphine Sulfate 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 Morphine Sulfate Injection?

DBL Morphine Sulfate Injection contains the active ingredient morphine sulfate pentahydrate. DBL Morphine Sulfate Injection is a pain reliever that belongs to a group of medicines called opioid analgesics. It is most commonly used for short-term relief of 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 Morphine Sulfate Injection?](#) in the full CMI.

2. What should I know before treatment with DBL Morphine Sulfate Injection?

You should not be given DBL Morphine Sulfate Injection if you have ever had an allergic reaction to morphine 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 Morphine Sulfate Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Morphine Sulfate 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 Morphine Sulfate Injection given?

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

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

5. What should I know during treatment with DBL Morphine Sulfate Injection?

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

Drinking alcohol	<ul style="list-style-type: none"> Do not drink alcohol while you are being treated with morphine.
Looking after your medicine	<ul style="list-style-type: none"> If you are being given DBL Morphine Sulfate 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 Morphine Sulfate 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, mood changes. If you experience any signs of an allergic reaction, severe drowsiness, slow or troubled breathing, severe weakness, agitation, hallucinations, unconsciousness, seizures, slow or rapid heart beat, difficulty in urinating, 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

Morphine 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

Morphine 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

Morphine 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 morphine 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 morphine

Using morphine 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 morphine.

DBL™ Morphine Sulfate Injection

Active ingredient(s): *morphine sulfate pentahydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Morphine Sulfate 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 Morphine Sulfate Injection.**

Where to find information in this leaflet:

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

1. Why am I being treated with DBL Morphine Sulfate Injection?

DBL Morphine Sulfate Injection contains the active ingredient morphine sulfate pentahydrate. DBL Morphine Sulfate Injection is a pain reliever that belongs to a group of medicines called opioid analgesics. Morphine acts in the brain and spinal cord.

DBL Morphine Sulfate Injection is used most commonly for short-term relief of severe pain. It may also be used just before or during an operation to help the anaesthetic work better.

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

Your doctor may have prescribed morphine for another reason.

2. What should I know before treatment with DBL Morphine Sulfate Injection?

Warnings

Do not use DBL Morphine Sulfate Injection if you:

- are allergic to any medicine containing morphine, any of the ingredients listed at the end of this leaflet, or any other similar medicines.

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.

- have severe bronchial asthma or severe disease relating to the lungs
- have shallow or difficulty breathing
- are suffering from acute alcoholism
- are undergoing treatment with monoamine oxidase (MAO) inhibitors (e.g. phenelzine, tranylcypromine, moclobemide or selegiline), or have stopped MAO inhibitor treatment during the last fourteen days
- have an irregular heart beat (arrhythmia)
- have severe liver problems
- have severe central nervous system depression
- have diabetic acidosis where there is danger of coma
- have had recent biliary tract surgery or biliary colic
- have obstruction of the gastrointestinal tract
- have a condition where the small bowel does not work properly (paralytic ileus)
- have diarrhoea caused by antibiotic-induced large bowel inflammation or by poisoning
- have a rare adrenal gland tumour near the kidney (phaeochromocytoma)

- have heart failure after lung disease
- have a head injury, brain tumour or increased pressure in the head or are comatose.

Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
 - epilepsy, convulsions, fits or seizures
 - underactive thyroid gland (hypothyroidism) and/or adrenal gland (Addison's disease)
 - enlarged prostate or problems with urination
 - fast heart beat (tachycardia)
 - liver problems
 - kidney problems
 - any bowel disorders or ulcerative colitis
 - biliary tract disease or inflammation of the pancreas
 - myasthenia gravis
 - snoring or sleep apnoea (you temporarily stop breathing or have difficulty breathing while asleep)
 - long-standing pain not related to cancer
 - unexplained increase in pain, increased levels of pain with increasing opioid medication or sensitivity not associated with the original pain.
- 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 Morphine Sulfate 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?](#)

Premature infants

DBL Morphine Sulfate Injection must not be given to premature infants or during labour for delivery of premature infants.

Pregnancy and breastfeeding

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

Talk to your doctor if you are breastfeeding or intend to breastfeed. As morphine passes into breast milk, breastfeeding is not recommended while you are being given morphine.

Your doctor or pharmacist can discuss with you the risks and benefits involved.

Addiction

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

Physical dependency

As with all other opioid containing products, your body may become used to you using morphine. 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 morphine 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 manage this.

Tolerance

Tolerance to morphine may develop, which means that the effect of the medicine may decrease. If this happens, a higher dose of morphine 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.

Morphine 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 Morphine Sulfate 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) i.e. 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

- cimetidine, a medicine used to treat stomach or duodenal ulcers, or reflux
- diuretics (fluid tablets)
- other medicines which may make you drowsy such as sleeping tablets, tablets to calm your nerves, sedatives, tranquilisers, general anaesthetics, hypnotics and muscle relaxants
- benzodiazepines and other medicines to treat anxiety, acute stress reactions, agitation, tremor e.g. diazepam, alprazolam or lorazepam
- anti-diarrhoeal medications e.g. loperamide and kaolin
- medicines to treat mental disorders (antipsychotics)
- other opioid analgesics or strong painkillers
- some antihistamines
- some heart medications e.g. beta blocker
- medicines that lower your blood pressure (antihypertensives)
- warfarin, a medicine used to thin the blood
- medicines used to reduce risk of blood clots or stroke e.g. clopidogrel, prasugrel and ticagrelor
- zidovudine or ritonavir, medicines used to treat HIV infection
- medicines used for seizures such as gabapentinoids e.g. gabapentin and pregabalin
- cannabis
- atropine
- some medicines used to treat infections e.g. rifampicin and ciprofloxacin.

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 morphine or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

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 Morphine Sulfate Injection.

4. How is DBL Morphine Sulfate Injection given?

How much is given

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

How is it given

- Your doctor or nurse will usually give DBL Morphine Sulfate Injection to you.

- DBL Morphine Sulfate 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 morphine you wish to receive. On experiencing pain, you can press a button, which allows a dose of morphine to be administered to you. To prevent you from receiving too much morphine, there is a "lockout" period built into the pump which prevents continuous injection of morphine.

Your doctor will decide the most appropriate way for you to be given DBL Morphine Sulfate Injection.

If you use too much (overdose)

If you think that you have received too much morphine, you may need urgent medical attention.

If you or someone else receive too much (overdose), 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 has accidentally used morphine that was prescribed for you.

Symptoms of an overdose may include:

- slow, unusual or difficult breathing
- drowsiness, dizziness or unconsciousness

- severe weakness
- slow or weak heart beat
- nausea or vomiting
- convulsions or fits
- 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.

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

5. What should I know during treatment with DBL Morphine Sulfate Injection?

As morphine may cause nausea and vomiting, your doctor is likely to prescribe medicine for you to take/ receive before the morphine, to stop you feeling sick.

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

Things you should do

- If you are about to be started on any new medicine, tell your doctor, dentist and pharmacist that you are being given morphine.

- Tell any doctors, dentists and pharmacists who treat you that you are being given morphine.
- If you plan to have surgery that needs a general anaesthetic, tell the surgeon or anaesthetist that you are being given morphine. It may affect other medicines used during surgery.
- If you become pregnant while you are being treated with morphine, tell your doctor or pharmacist immediately.
- Tell your doctor, pharmacist or nurse if you have any concerns about being given morphine.

Things you should not do

- Do not use DBL Morphine Sulfate Injection to treat any other complaints unless your doctor tells you to.
- Do not give DBL Morphine Sulfate Injection to anyone else, even if they have the same condition as you.
- Do not stop using DBL Morphine Sulfate Injection or lower the dosage without checking with your doctor or pharmacist. If you have been using DBL Morphine Sulfate Injection for more than two weeks, you may experience unpleasant feelings if you stop suddenly. Your doctor will probably want you to gradually reduce the amount of morphine 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 morphine.

Driving or using machines

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

DBL Morphine Sulfate Injection may cause drowsiness and impairment of coordination in some people. Do not do anything else that could be dangerous if you are drowsy or feeling uncoordinated.

Make sure you know how you react to morphine.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

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

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

- Do not store DBL Morphine Sulfate Injection or any other medicine in the bathroom or near a sink.
- Do not leave it on a window sill or in the car.

- Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

When to discard your medicine

Do not use this medicine after the expiry date.

If your doctor tells you to stop using DBL Morphine Sulfate 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.

Do not stop using morphine 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● confusion● sweating or flushing● nausea and/or vomiting● constipation● reduced libido, erectile dysfunction or no menstrual periods● loss of appetite or taste changes● pain and irritation at the injection site● red, itchy skin● blurred vision● dry mouth● mood changes	<p>Speak to your doctor if you have any of these 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">● any signs of an allergic reaction to morphine such as:<ul style="list-style-type: none">○ 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● severe drowsiness● slow or troubled breathing● severe weakness● agitation● hallucinations● seizures (fits)● unconsciousness● slow or rapid heart beat● difficulty in urinating	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these side effects.</p> <p>These are very serious side effects. 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 Morphine Sulfate Injection contains

Active ingredient (main ingredient)	Morphine sulfate pentahydrate
Other ingredients (inactive ingredients)	Sodium chloride Hydrochloric acid (to adjust pH) Water for injections

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

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

What DBL Morphine Sulfate Injection looks like

DBL Morphine Sulfate Injection is a clear slightly yellow to clear yellow solution in a coloured glass ampoule.

It is available in the following strengths:

5 mg/1 mL AUST R 121754

10 mg/1 mL AUST R 101240

15 mg/1 mL AUST R 101243

30 mg/1 mL AUST R 121755

Not all presentations may be marketed.

Sponsor

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www.pfizermedicalinformation.com.au

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