

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. It may be given by an injection or infusion, or you may be given a "patient-controlled analgesia" (PCA) device to use.

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">DBL Morphine can affect driving and safe use of machinery and tools. You may be tested for the presence of this drug whilst driving in New Zealand.. 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 urinating, severe skin rash/mouth sores or severe upper abdominal pain, you may need urgent medical attention or hospitalisation. Repeated use of morphine can result in it becoming less effective (you become tolerant to it) and it can also lead to dependence, abuse and addiction, which may result in life-threatening overdose.

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 breathing problems

Morphine injection can cause serious, 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 if you 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 very drowsy or increase your risk of decreased awareness, serious breathing problems, coma or death. Such medicines include: sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol. Your doctor will minimise the dose and duration of use of morphine (and/or the other drugs) 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, nurse 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?

This medicine has been prescribed for you and should not be given to anyone else.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you expect during treatment with morphine (in terms of pain control), when and for how long morphine will be given, when it should be stopped and how to do this safely.

Morphine should not be used for longer than necessary.

Repeated use of morphine can result in it becoming less effective (you become tolerant to it) and it can also lead to dependence, abuse and addiction, which may result in life-threatening overdose.

The signs and symptoms of this are explained further down in this document.

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 asthma or severe lung disease such as bronchitis (i.e. coughing spells with thick phlegm and breathlessness), emphysema (which leaves you struggling for breath) or COPD (Chronic Obstructive Pulmonary Disease), which causes difficulty breathing, mucus or sputum production and wheezing.
- have shallow or difficulty breathing
- are suffering from alcoholism or delirium tremens ("DTs", "the shakes") 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 (14) days
- have an irregular heartbeat (arrhythmia), or heart flutter
- have heart failure after lung disease (cor pulmonale)
- have severe liver or kidney problems
- have severe decreased level of consciousness
- have diabetic acidosis where there is danger of coma
- have had recent biliary tract surgery or biliary colic (which causes severe stomach cramps)
- have obstruction of the gastrointestinal tract or require abdominal surgery
- have a condition where the small bowel does not work properly or is blocked (paralytic ileus)
- have severe diarrhoea, or diarrhoea caused by antibiotic-induced large bowel inflammation or poisoning
- have a rare adrenal gland tumour near the kidney (phaeochromocytoma)
- have a severely deformed spine
- are suffering from mental illness brought on by an infection
- have a head injury, brain tumour or increased pressure in the head/brain/spinal cord or are unconscious.
- are having fits/convulsions
- have sickle cell disease (an inherited red blood cell disorder)

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)
 - low blood pressure
 - liver problems
 - kidney problems
 - any bowel problems or ulcerative colitis
 - problems with your bile duct or pancreas
 - myasthenia gravis

- snoring or sleep apnoea (you temporarily stop breathing or have difficulty breathing while asleep)
- feel weak or very run down
- 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.

Tell your doctor if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after being given morphine or other opioids.

Acute generalised exanthematous pustulosis (AGEP) has been reported in association with morphine treatment. Symptoms usually occur within the first 10 days of treatment.

Sleep-related breathing disorders

DBL Morphine Sulfate Injection can cause sleep-related breathing problems such as sleep apnoea (breathing pauses during sleep), which causes low oxygen levels in your blood. The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties staying asleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

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.

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?](#)

Addiction

Taking this medicine regularly, especially for a long period of time, can lead to addiction.

Talk with your doctor before taking this medicine if you:

- are using drugs or have used drugs in the past, especially amphetamines
- are or have ever been addicted to opioids, alcohol, prescription medicines or illegal drugs
- have previously suffered withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted to morphine if:

- you or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs
- you are a smoker, or use vapes
- you have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

Addiction can make you feel that you are no longer in control of how much medicine you need to use or how often you need to use it.

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 your pain.

Do not try to inject morphine obtained from tablets or patches. This can cause serious side effects and can result in death.

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.

Dependence can make you feel that you are no longer in control of how much medicine you need to use or how often you need to use it.

If you notice any of the following signs whilst using DBL Morphine Sulfate Injection, it could be a sign that you have become dependent or addicted:

- you need to use morphine for longer than advised by your doctor
- you need to use more than the recommended dose
- you are using morphine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- you have made repeated, unsuccessful attempts to quit or control the use of morphine
- when you stop using morphine you feel unwell, and you feel better once using the medicine again ('withdrawal effects').

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely.

Tolerance

Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). If this happens, a higher dose of morphine may be needed to maintain the same effect, which may result in life-threatening overdose.

Speak with your doctor, nurse or pharmacist if you feel you need more morphine to get the same level of pain relief, as this may mean you are becoming tolerant to the effects of morphine or are becoming addicted to it.

Your doctor will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

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, irritability, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, feeling or being sick or having diarrhoea
- increased heart rate, breathing rate or pupil size
- feeling your heartbeat (palpitations), increased blood pressure,
- watery eyes, runny nose, shaking, chills or yawning
- increased sweating or body temperature
- hairs standing on end.
- muscle twitching
- seizures.

Morphine given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Your doctor will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop using the medicine suddenly as you will be more likely to experience withdrawal symptoms.

The risk of these side effects can increase with a higher dose and longer duration of use. However, it is also important to keep your pain under control. Your doctor can advise you on how to manage this.

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:

- These medicines may be affected by morphine or may affect how well it works. You may need different amounts

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.

- slow, unusual or difficult breathing
- drowsiness, confusion, dizziness or unconsciousness
- severe weakness

- slow or weak heartbeat
- nausea or vomiting
- pneumonia from inhaling vomit (with breathlessness, cough and fever)
- convulsions or fits
- pale and cold skin.

You should immediately:

- phone the Poisons Information Centre (by calling **0800 POISON**, or **0800 764 766**), 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 from 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.

DBL Morphine has the potential to affect driving and has been identified as having a high risk to road safety and it is an offence to drive while impaired. You may be tested for the presence of this drug in your blood whilst driving in New Zealand.

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, nurse 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
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<ul style="list-style-type: none"> • drowsiness, dizziness or unsteadiness • light-headedness, fainting • headache • confusion or mental clouding • sweating or flushing • nausea and/or vomiting (feeling and/or being sick) • constipation or abdominal pain • reduced libido, erectile dysfunction or no menstrual periods • shivering, shaking or muscle twitching or jerking • loss of appetite or taste changes • pain and irritation at the injection site • red, itchy skin • blurred vision, double vision, small pupils, unusual eye movements • dry mouth, difficulty speaking • mood changes or fatigue • sleep-related breathing issues (sleep apnoea) • feeling faint on standing up • unusual sensitivity to touch or increased sensitivity to pain, despite the fact that you are taking increasing doses (hyperaesthesia) • higher or lower blood pressure 	<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>
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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 (imagining things) • seizures (fits, convulsions) • unconsciousness • slow or rapid heartbeat • palpitations (skipped, extra or irregular heartbeat) • difficulty in urinating • blistering, widespread scaly skin or pus-filled spots together with fever • severe upper abdominal pain possibly radiating to the back, with nausea, vomiting or fever 	<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 Medsafe online at <https://pophealth.my.site.com/carmreportnz/s/>. 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.

DBL Morphine Sulfate injection does not contain any antioxidant or preservatives.

What DBL Morphine Sulfate Injection looks like

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

It is available in the following strengths:

5 mg/1 mL

10 mg/1 mL

15 mg/1 mL

30 mg/1 mL

Not all presentations may be marketed.

Sponsor

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