

# DBL™ Morphine Sulfate Injection

Morphine sulfate pentahydrate

## Consumer Medicine Information

### 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 sulfate 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 sulfate 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.

### What is in this leaflet

This leaflet answers some common questions about DBL Morphine Sulfate Injection (Morphine). 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 has weighed the risks of you being given Morphine Injection against the benefits they expect it will have for you.

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

**Keep this leaflet in a safe place.**

You may need to read it again.

### What Morphine is used for

Morphine is a pain reliever that belongs to a group of medicines called opioid analgesics.

Morphine acts in the brain and spinal cord.

It 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.

Morphine 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 morphine suddenly.

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

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

### Before you are given Morphine

*When you must not be given it*

**Do not use Morphine Injection if you have an allergy to:**

- any medicine containing morphine
- any of the ingredients listed at the end of this leaflet
- any other similar medicines.

Some of the 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.

**You should not be given morphine if:**

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

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

**Do not use Morphine Injection after the expiry date (EXP) printed on the pack.**

If you are given this medicine after the expiry date has passed, it may not work as well.

**Do not use Morphine Injection if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should be given this medicine, talk to your doctor or pharmacist.**

### Before you are given it

**Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.**

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

- epilepsy, convulsions, fits or seizures
- under-active thyroid gland (hypothyroidism) and/or adrenal gland (Addison's disease)
- enlarged prostate or problems with urination
- tachycardia, fast heart beat
- 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.

**Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding or plan to breast-feed.**

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

As morphine passes into breast milk, breast-feeding is not recommended while you are being given morphine.

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

### Addiction

You can become addicted to morphine sulfate even if you use it exactly as prescribed. Morphine sulfate 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 morphine sulfate. Using it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking morphine

sulfate suddenly, so it is important to take it exactly as directed by your doctor.

### **Tolerance**

Tolerance to morphine sulfate 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.

Morphine Injection 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 any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and morphine 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-HT<sub>3</sub> receptor antagonists)
- selegiline, a monoamine oxidase inhibitor used to treat Parkinson's disease
- alcohol
- cimetidine (Magicul), 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
- anti-diarrhoeal medications (e.g. loperamide and kaolin)
- medicines to treat mental disorders (antipsychotics), other opioid analgesics or strong painkillers,
- some antihistamines and some heart medications (e.g. beta blocker).
- benzodiazepines (and other medicines) to treat anxiety, acute stress reactions, agitation, tremor, such as diazepam (Valium), alprazolam or lorazepam

- medicines that lower your blood pressure (antihypertensives)
- warfarin (Marevan, Coumadin), a medicine used to thin the blood
- zidovudine (Retrovir, Combivir, Trizivir) a medicine used to treat HIV infection, ritonavir (Kaletra, Norvir), a medicine used to treat HIV infection.
- medication used to reduce risk of blood clots or stroke (eg clopidogrel, prasugrel and ticagrelor.)
- medications 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. You must not drink alcohol while using morphine sulfate.

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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while receiving this medicine.

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### **How Morphine is given**

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

#### *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 it is given*

Your doctor or nurse will usually give morphine to you.

Morphine 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 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 morphine.

#### *If you use too much (overdose)*

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

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 have accidentally used morphine sulfate 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
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits

If you think you or someone else may have used too much morphine, 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.

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

You may need urgent medical attention.

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### **While you are being given Morphine Injection**

#### *Things you must 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 other 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.**

#### *Things you must not do*

**Do not use Morphine Injection to treat any other complaints unless your doctor tells you to.**

**Do not give Morphine Injection to anyone else, even if they have the same condition as you.**

**Do not stop using morphine, or lower the dosage without checking with your doctor or pharmacist.**

If you have been using morphine for more than two weeks, you may experience unpleasant feelings if you stop morphine 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 approved or recommended by a doctor or pharmacist who knows you are being given morphine.**

#### *Things to be careful of*

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

Morphine may cause drowsiness, and impairment of co-ordination, in some people.

Make sure you know how you react to morphine.

**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 morphine, unless otherwise advised by your doctor or pharmacist, as drowsiness and coordination impairment may be worse.**

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.

**Tell your doctor, pharmacist or nurse if you have any concerns about being given morphine.**

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#### Side effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given morphine.**

Morphine 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 attention 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.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**If you get any side effects, do not stop using morphine 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
- 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
- blurred vision
- dry mouth
- mood changes
- red, itchy skin.

These are the more common side effects of Morphine.

Mostly they are mild and short-lived.

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

- any signs of an allergic reaction to morphine (which are listed at the start of this leaflet)

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

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

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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

You may not experience any of them.

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#### After being given Morphine

##### Storage

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

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

**Do not store Morphine 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 children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

##### Disposal

**If your doctor tells you to stop using Morphine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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#### Product description

##### What it looks like

Morphine comes in a coloured glass ampoule containing a clear colourless to slightly yellow solution.

##### Ingredients

Morphine contains 5, 10, 15, or 30 milligrams of morphine sulfate pentahydrate as the active ingredient.

Other ingredients:

- sodium chloride
- hydrochloric acid (to adjust pH)
- water for injections.

Morphine do 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

Morphine is available in the following strengths:

#### Strength

#### AUST R

5 milligrams/1 mL	121754
10 milligrams/1 mL	101240
15 milligrams/1 mL	101243
30 milligrams/1 mL	121755

™ = Trademark

This leaflet was updated in April 2021.