DBL™ Morphine Sulfate Injection DBL™ Morphine Tartrate Injection

Morphine Sulfate Pentahydrate (MOR-feen SUL-fate Pent-a-hy-drate) Morphine Tartrate (MOR-feen TAR-trate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Morphine Sulfate Injection and DBL™ Morphine Tartrate 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 Injection 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 relief of severe pain. It may also be used just before or during an operation to help the anaesthetic work better.

Your doctor may have prescribed morphine for another reason.

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

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 Injection

When you must not be given it

You should not be given morphine if you have an allergy to morphine, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to morphine 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 any other lung or breathing problems
- you are suffering from acute alcoholism
- you are undergoing treatment with monoamine oxidase (MAO) inhibitors (eg phenelzine, tranylcypromine, moclobemide or selegeline), or have stopped MAO inhibitor treatment during the last fourteen days

- you have an irregular heart beat (arrhythmia)
- you have severe liver problems
- you have a head injury, brain tumour or increased pressure in the head.

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

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 you are not sure whether you should be given morphine, 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 morphine during pregnancy.

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

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

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
- liver problems
- · kidney problems
- any bowel disorders or ulcerative colitis,
- biliary tract disease or inflammation of the pancreas
- · myasthenia gravis.

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

Taking other medicines

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

Some medicines and morphine may interfere with each other. These include:

 antidepressants which belong to the group of medicines called monoamine oxidase inhibitors. ie. moclobemide, phenelzine, tranylcypromine

- selegeline, a monoamine oxidase inhibitor used to treat Parkinson's disease
- alcohol
- cimetidine (Tagamet, 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, hypnotics and muscle relaxants, medicines to treat mental disorders, other strong painkillers, some antihistamines and some heart medication. 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.

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 may have more information on medicines to be careful with or avoid while receiving Morphine Injection.

How Morphine Injection is 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 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 take 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.

Immediately telephone your doctor or the Poisons Information Centre (Australia on 131 126 or New Zealand on 0800 764 766) 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 Morphine.

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

You may need urgent medical attention.

While you are being given Morphine Injection

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given morphine.

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

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given morphine.

If you become pregnant while you are being treated with morphine, tell your doctor or pharmacist immediately.

Things you must not do

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

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

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.

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 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 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
- · 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 Injection. 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 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 being given Morphine Injection

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 Injection or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

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.

Disposa

If your doctor or pharmacist tells you to stop using Morphine Injection or the injections have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

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

DBLTM Morphine Tartrate Injection comes in a glass ampoule containing a clear colourless to almost colourless solution.

Ingredients

DBLTM Morphine Sulfate Injection

Active ingredient:

morphine sulfate pentahydrate

Other ingredients:

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

DBLTM Morphine Tartrate Injection

Active ingredient:

morphine tartrate

Other ingredients:

- · sodium metabisulphite
- water for injections

DBLTM Morphine Sulfate Injection and DBLTM Morphine Tartrate Injection do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

DBL™ Morphine Sulfate Injection and DBL™ Morphine Tartrate Injection are supplied by:

Australian Sponsor:

Pfizer Australia Pty Ltd SYDNEY, NSW Toll Free Number 1800 675 229 www.pfizer.com.au

DBL™ Morphine Sulfate Injection is available in the following strengths:

Strength	Aust R
5 mg/ 1 mL	121754
10 mg/ 1 mL	101240
15 mg/ 1 mL	101243
30 ma/ 1 mL	121755

DBLTM Morphine Tartrate Injection is available in the following strengths:

Strength Aust R 120 mg/ 1.5 mL 16324 400 mg/ 5.0 mL 47257

This leaflet was updated in: April 2019.