Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL Magnesium Sulfate Concentrated Injection. 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 magnesium sulfate heptahydrate 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.

You may need to read it again.

What DBL Magnesium Sulfate Concentrated Injection is used for

This medicine is used to:

- treat very low levels of magnesium in the body
- prevent low levels of magnesium in patients receiving total parenteral nutrition
- prevent and treat seizures (fits) in pregnant women due to pre-eclampsia or eclampsia (also called toxaemia of pregnancy).

This medicine works by providing a source of magnesium for your body to use.

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

Before you are given DBL Magnesium Sulfate Concentrated Injection

When you must not be given it You must not be given DBL Magnesium Sulfate Concentrated Injection if you have an allergy to:

• any medicine containing magnesium. 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 must not be given this medicine if you have:

- heart block (a slow or irregular heart beat)
- severe kidney disease.

This medicine must not be given to pregnant women in the 2 hours prior to delivery, unless it is the only therapy available to prevent or treat eclamptic seizures.

Use of this medicine in pregnancy for prolonged periods of time (5-7 days duration) should be avoided unless indicated by your doctor.

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

Before you are given it

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

Tell your doctor if you have or have had any of the following medical conditions:

kidney problems.

Tell your doctor if you are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given magnesium sulfate heptahydrate.

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 magnesium sulfate heptahydrate may interfere with each other. These include:

- digoxin, a medicine used to treat heart failure
- central nervous system depressants (medicines that cause drowsiness or sedation)
- neuromuscular blocking agents (medicines used to relax muscles during surgery)
- nifedipine, a medicine used to treat high blood pressure or angina.

These medicines may be affected by magnesium sulfate heptahydrate or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist may have more information on medicines to be careful; with or avoid while being given this medicine.

How DBL Magnesium sulfate concentrated injection is given

How much is given

Your doctor will decide what dose of magnesium sulfate heptahydrate you will receive and how long you will receive it for. This depends on your medical condition and other factors, such as your weight.

How it is given

DBL Magnesium Sulfate Concentrated Injection may be given as an injection into the vein (intravenous) or into the muscle (intramuscular).

This medicine must only be given by a doctor or nurse.

If you take too much (overdose)
As DBL Magnesium Sulfate Concentrated
Injection is given to you under the

Injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Immediately telephone your doctor or the Poisons Information Centre on 13 11 26 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 DBL Magnesium Sulfate Concentrated Injection. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of a magnesium sulfate heptahydrate overdose may include the side effects listed below in the 'Side effects' section, but are usually of a more severe nature.

While you are being given DBL Magnesium Sulfate Concentrated Injection

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are receiving magnesium sulfate heptahydrate.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are being given this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must do

Be careful driving or operating machinery until you know how magnesium sulfate heptahydrate affects you.

This medicine may cause blurred or double vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given magnesium sulfate heptahydrate.

Magnesium sulfate heptahydrate helps most people with low magnesium levels, or in toxaemia of pregnancy, but 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.

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.

Tell your doctor or nurse if you notice any of the following and they worry you:

 pain or irritation at the injection site (usually following intramuscular injection).

This side effect is usually mild and short-lived.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- · nausea or vomiting
- flushing
- dizziness or fainting (due to low blood pressure)
- · drowsiness or sedation
- · muscle weakness
- · blurred or double vision.
- sweating

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor or nurse immediately:

- · muscle paralysis
- · difficulty breathing
- · changes in heart rate
- passing little or no urine.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or nurse if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

After being given DBL™ Magnesium Sulfate Concentrated Injection

Storage

DBL Magnesium Sulfate Concentrated Injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25C.

Product description

What it looks like

DBL Magnesium Sulfate Concentrated Injection is a clear, colourless solution packaged in glass ampoules.

Ingredients

Each ampoule of DBL Magnesium Sulfate Concentrated Injection contains

magnesium sulfate heptahydrate as the active ingredient.

Each ampoule also contains:

water for injection.

Sponsor

DBL Magnesium Sulfate Concentrated Injection is supplied by:

Australian Sponsor:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

DBL Magnesium Sulfate Concentrated Injection is supplied in the following strength:

 2.465 grams in 5mL ampoule AUST R 16311

This leaflet was updated in September 2021.