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.

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

DBL Magnesium Sulfate Concentrated Injection contains the active ingredient magnesium sulfate heptahydrate. This medicine works by providing a source of magnesium for the body to use. DBL Magnesium Sulfate Concentrated Injection 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).

For more information, see Section 1. Why am I being treated with DBL Magnesium Sulfate Concentrated Injection? in the full CMI.

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

Do not use if you have ever had an allergic reaction to medicines containing magnesium or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any heart conditions or kidney problems.

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 Magnesium Sulfate Concentrated Injection? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Magnesium Sulfate Concentrated Injection and affect how it works. A list of these medicines is in Section <u>3. What if I am taking other medicines?</u> in the full CMI.

4. How is DBL Magnesium Sulfate Concentrated Injection given?

- DBL Magnesium Sulfate Concentrated Injection is given as an injection into a vein or muscle by a doctor or nurse.
- Your doctor will decide how much DBL Magnesium Sulfate Concentrated Injection is needed. It will depend on your condition and other factors such as your weight.

More instructions can be found in Section 4. How is DBL Magnesium Sulfate Concentrated Injection given? in the full CMI.

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

Things you should do	• Tell any doctor or nurse giving you this medicine if you are about to be started on any new medicine; you are pregnant or planning to become pregnant; or you are breastfeeding or planning to breastfeed.
Driving or using machines	DBL Magnesium Sulfate Concentrated Injection may cause blurred or double vision in some people. If you have any of these symptoms, do not drive or operate machinery.
Drinking alcohol	Tell your doctor if you drink alcohol.
Looking after your medicine	 DBL Magnesium Sulfate Concentrated Injection is stored in the pharmacy or on the ward. Keep in a cool dry place, protected from light where the temperature stays below 25°C.

For more information, see Section <u>5. What should I know during treatment with DBL Magnesium Sulfate Concentrated Injection?</u> in the full CMI.

6. Are there any side effects?

Common side effects are pain or irritation at the injection site usually following intramuscular injection. Serious side effects are rare and include nausea or vomiting, flushing, dizziness or fainting due to low blood pressure, drowsiness, muscle weakness, blurred or double vision, sweating. Tell your doctor immediately if you experience muscle paralysis, difficulty breathing, changes in heart rate or if you are passing little or no urine.

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.

DBL™ Magnesium Sulfate Concentrated Injection

Active ingredient(s): magnesium sulfate heptahydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Magnesium Sulfate Concentrated 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 Magnesium Sulfate Concentrated Injection.

Where to find information in this leaflet:

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

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

3. What if I am taking other medicines?

4. How is DBL Magnesium Sulfate Concentrated Injection given?

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

6. Are there any side effects?

7. Product details

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

DBL Magnesium Sulfate Concentrated Injection contains the active ingredient magnesium sulfate heptahydrate. This medicine works by providing a source of magnesium for your body to use.

DBL Magnesium Sulfate Concentrated Injection 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)

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

Warnings

Do not use DBL Magnesium Sulfate Concentrated Injection if:

• you are allergic to any medicine containing magnesium, or any of the ingredients listed at the end of this leaflet.

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.

Always check the ingredients to make sure you can use this medicine.

you have heart block (a slow or irregular heart beat)

• severe kidney disease

Check with your doctor if you:

- have or have had any other medical conditions including
 kidney problems
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes

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

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 <u>6. Are there any side effects</u>?

This medicine is not addictive.

Pregnancy and breastfeeding

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

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

If you have not told your doctor about any of the above, tell them before you are given DBL Magnesium Sulfate Concentrated Injection.

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 Magnesium Sulfate Concentrated Injection and affect how it works. 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. 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 Magnesium Sulfate Concentrated Injection.

4. How is DBL Magnesium Sulfate Concentrated Injection given?

How much is given

- Your doctor will decide what dose of DBL Magnesium Sulfate Concentrated Injection 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 is DBL Magnesium Sulfate Concentrated Injection 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 too much DBL Magnesium Sulfate Concentrated Injection is given

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

Symptoms of an overdose may include the side effects listed under Section <u>6. Are there any side effects?</u>

If you think that you have been given too much DBL Magnesium Sulfate Concentrated Injection, you may need urgent medical attention.

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 Magnesium Sulfate Concentrated Injection?

Things you should do

Tell any doctor or nurse giving you this medicine if you:

- are about to be started on any new medicine
- are planning to become pregnant. Tell your doctor immediately if you become pregnant during treatment with this medicine
- are breastfeeding or planning to breastfeed
- are about to have any blood tests as it may interfere with the results of some tests

Remind any doctor, dentist or pharmacist you see that you are being given DBL Magnesium Sulfate Concentrated Injection.

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.

Driving or using machines

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

DBL Magnesium Sulfate Concentrated Injection 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

How is DBL Magnesium Sulfate Concentrated Injection stored

- DBL Magnesium Sulfate Concentrated Injection is stored in the pharmacy or on the ward.
- Store below 25°C. Keep in a cool dry place, protected from light.

Keep it where young children cannot reach it.

When to discard DBL Magnesium Sulfate Concentrated Injection

DBL Magnesium Sulfate Concentrated Injection diluted solutions should be prepared, stored and used within 24 hours. Any remaining contents should be discarded after 24 hours.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. DBL Magnesium Sulfate Concentrated Injection helps most people with low magnesium levels, or in toxaemia of pregnancy, but may have unwanted side effects in a few people. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
 Pain or irritation at the injection site (usually following intramuscular injection). 	Speak to your doctor if you have any of these common side effects and they worry you. This side effect
	is usually mild and short-lived.

Serious side effects

Serious side effects	What to do
 Nausea or vomiting Flushing Dizziness or fainting (due blood pressure) Drowsiness or sedation Muscle weakness Blurred or double vision 	to low Tell your doctor or nurse as soon as possible if you notice these serious side effects.
Sweating	These side effects are rare and may require medical attention.
 Muscle paralysis Difficulty breathing Changes in heart rate Passing little or no urine 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.
	These side effects are very rare. You may need urgent medical attention or hospitalisation.

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 <u>www.tga.gov.au/</u> <u>reporting-problems</u>. 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 Magnesium Sulfate Concentrated Injection contains

Active ingredient (main ingredient)	Magnesium sulfate heptahydrate
Other ingredients (inactive ingredients)	Water for injections

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

What DBL Magnesium Sulfate Concentrated Injection looks like

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

2.465 g/5 mL ampoule

Australian Registration Number: AUST R 16311

Who distributes DBL Magnesium Sulfate Concentrated Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedinfo.com.au

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