DBL™ Diazoxide Injection BP

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 given DBL Diazoxide Injection?

DBL Diazoxide Injection contains the active ingredient diazoxide. DBL Diazoxide Injection is used to quickly lower very high blood pressure in emergency situations or prevent bleeding during diagnostic procedures if you have high blood pressure.

For more information, see Section 1. Why am I using DBL Diazoxide Injection? in the full CMI.

2. What should I know before receiving DBL Diazoxide Injection?

Do not receive DBL Diazoxide Injection if you have ever had an allergic reaction to DBL Diazoxide Injection, any of the ingredients listed at the end of the CMI or other thiazides, such as hydrochlorothiazide. You must not receive DBL Diazoxide Injection if you have high blood

pressure due to mechanical abnormalities of the heart (such as an AV shunt).

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 I use DBL Diazoxide Injection? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Diazoxide 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 Diazoxide Injection given?

- Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.
- DBL Diazoxide Injection is given as an injection into a vein (intravenously). It must only be given by a nurse or doctor.

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

5. What should I know while receiving DBL Diazoxide Injection?

Things you must do	• Stay lying down for at least 30 minutes after receiving this medicine. • Remind any doctor, nurse or pharmacist you visit that you are being treated with DBL Diazoxide Injection. • Tell your doctor if you are pregnant.
Driving or using machines	• Be careful driving or operating machinery until you know how diazoxide affects you. • This medicine may cause dizziness, light-headedness or tiredness 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	• Be careful when drinking alcohol while you are receiving this medicine.

	• If you drink alcohol, symptoms such as dizziness or light-headedness may be worse.
Looking after your medicine	• DBL Diazoxide 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 25°C.

For more information, see Section 5. What should I know while receiving DBL Diazoxide Injection? in the full CMI.

6. Are there any side effects?

Side effects of this medicine include oedema (swelling of the hands feet or ankles), weight gain, flushing, feeling of warmth, burning or itching, headache, sweating, weakness, pain along the vein where the injection was given, nausea, vomiting, abdominal discomfort, lethargy or tiredness, thirst, passing large amounts of urine, blurred vision, shortness of breath, difficulty in breathing while lying down, chest pain or fullness, dizziness, light-headedness or fainting which may be due to very low blood pressure, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin, intolerance to

food, abdominal bloating, pain, swelling or discomfort, bloody stool, diarrhoea, constipation.
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™ Diazoxide Injection BP

Active ingredient(s): diazoxide (dye-a-ZOX-ide)

Consumer Medicine Information (CMI)

This leaflet provides important information about DBL Diazoxide 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 DBL Diazoxide Injection.**

Where to find information in this leaflet:

1. Why am I being given DBL Diazoxide Injection?
2. What should I know before receiving DBL Diazoxide Injection?
3. What if I am taking other medicines?
4. How is DBL Diazoxide Injection given?
5. What should I know while receiving DBL Diazoxide Injection?
6. Are there any side effects?
7. Product details

1. Why am I being given DBL Diazoxide Injection?

DBL Diazoxide Injection contains the active ingredient diazoxide.

DBL Diazoxide Injection is used to:

- quickly lower very high blood pressure in emergency situations
- prevent bleeding during diagnostic procedures if you have high blood pressure.

This medicine belongs to a group of medicines called vasodilators.

It works by widening blood vessels, which causes a decrease in blood pressure.

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.

2. What should I know before receiving DBL Diazoxide Injection?

Warnings

Do not receive DBL Diazoxide Injection if:

- you are allergic to diazoxide, or any of the ingredients listed at the end of this leaflet.
- you are allergic to other thiazides, such as hydrochlorothiazide.
- you have hypertension due to mechanical abnormalities of the heart (such as an AV shunt).

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.

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

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

- kidney problems
- diabetes
- circulation problems
- gout
- leucopenia (low numbers of white blood cells) or thrombocytopenia (low numbers of platelets).

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?

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.

Your doctor can discuss the risks and benefits involved.

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 and diazoxide may interfere with each other. These include:

- diuretics (fluid tablets)
- other medications used to treat high blood pressure.

These medicines may be affected by diazoxide, 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 and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

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 Diazoxide Injection.

4. How is DBL Diazoxide Injection given?

How much is given

- Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.

How it is given

- DBL Diazoxide Injection is given as an injection into a vein (intravenously). It must only be given by a nurse or doctor.

If you are given too much DBL Diazoxide Injection

As DBL Diazoxide Injection is given to you under the supervision of your doctor, it is very unlikely that you will receive an overdose.

Symptoms of an overdose may include the side effects listed below in Section 6. Are there any side effects?, but are usually of a more severe nature.

Speak to your doctor, nurse or pharmacist if you have any concerns.

5. What should I know while receiving DBL Diazoxide Injection?

Things you must do

Stay lying down for at least 30 minutes after receiving this medicine

You may feel light-headed or dizzy.

Keep all your doctor's appointments

- Keep all of your doctor’s appointments so that your progress can be checked.
- Your doctor may do some tests, such as glucose monitoring tests, from time to time to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor straight away if you:

- become pregnant while taking this medicine

Remind any doctor, nurse, dentist or pharmacist you visit that you are being given DBL Diazoxide Injection.

Driving or using machines

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

DBL Diazoxide Injection may cause dizziness, light-headedness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Children should be careful when riding bicycles or climbing trees.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, symptoms as dizziness or light-headedness may be worse.

Looking after your medicine

DBL Diazoxide 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 25°C.

Getting rid of any unwanted medicine

Your doctor, nurse or pharmacist will dispose of any left-over medicine.

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.

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

Side effects

Side effects	What to do
General disorders and administration site conditions: • oedema (swelling of the hands feet or ankles) • weight gain • flushing • feeling of warmth • burning or itching • headache • sweating • weakness • pain along the vein where the injection was given. **Gastrointestinal issues (stomach-related):** • nausea, vomiting • abdominal discomfort.	**Speak to your doctor or nurse if you have any of these side effects and they worry you.**

Side effects	What to do
Metabolism and nutrition disorders: • signs of high blood sugar levels such as lethargy or tiredness, headache, thirst, passing large amounts of urine, blurred vision **Heart problems:** • signs of heart problems such as shortness of breath, difficulty in breathing while lying down, chest pain or fullness, swelling of the feet or legs due to fluid build-up **Vascular disorder (circulatory system-related):** • dizziness, light-headedness or fainting which may be due to very low blood pressure **Allergic type reactions:** • signs of an allergic reaction such as those	**Call your doctor or nurse straight away if you notice any of these side effects.**

Side effects	What to do
listed at the start of this leaflet **Gastrointestinal issues (stomach-related):** • signs of severe inflammation of the bowel such as intolerance to food, abdominal bloating, pain, swelling or discomfort, bloody stool, diarrhoea, constipation.	

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 www.tga.gov.au/reporting-problems. 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 taking any of your medicines.

7. Product details

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

What DBL Diazoxide Injection contains

Active ingredient **(main ingredient)**	Diazoxide
Other ingredients **(inactive ingredients)**	Sodium hydroxide Water for injections

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

DBL Diazoxide Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What DBL Diazoxide Injection looks like

DBL Diazoxide Injection is a clear, colourless solution in a glass ampoule. It is available in packs of one ampoule.

DBL Diazoxide Injection is available in the following strength:

- 300mg/20mL ampoule (AUST R 16377)

Who distributes DBL Diazoxide Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229
www.pfizermedicalinformation.com.au

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