Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL^{TM} Diazoxide 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 diazoxide 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™ Diazoxide Injection is used for

This medicines 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. It is only available with a doctor's prescription.

Before you are given DBL™Diazoxide Injection

When you must not be given it

You must not be given $DBL^{\rm TM}$ Diazoxide Injection if you have an allergy to:

- diazoxide
- any of the ingredients listed at the end of this leaflet
- other thiazides, such as hydrochlorthiazide.

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 any of the following medical conditions:

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

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

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 if you have or have had any medical conditions:

- kidney problems
- diabetes

- · circulation problems
- gou
- leucopenia (low numbers of white blood cells) or thrombocytopenia (low numbers of platelets)

Tell your doctor if you are pregnant or intend to become pregnant or are breast-feeding. Your doctor can discuss the risks and benefits

If you have not told your doctor about any of the above, tell him/her before you are given $DBL^{TM}Diazoxide$ Injection.

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 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.

How DBL™ Diazoxide Injection is given

How much is given

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

How it is given

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

If you receive too much (overdose)

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

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand) 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™ Diazoxide Injection. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

Ask your doctor or pharmacist if you have any concerns.

While you are being given it

Things you must do

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

You may feel light-headed or dizzy.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given DBL^{TM} Diazoxide Injection.

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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

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.

Things to be careful of

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

This medicine may cause dizziness, lightheadedness 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.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, symptoms as dizziness or light-headedness may be worse.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given DBL^{TM} Diazoxide Injection.

This medicine 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.

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

You may not experience any of them.

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

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

- 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.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- signs of high blood sugar levels such as lethargy or tiredness, headache, thirst, passing large amounts of urine, blurred vision
- signs of heart failure such as shortness of breath, swelling of the feet or legs due to fluid build-up
- dizziness, light-headedness or fainting which may be due to very low blood pressure
- signs of an allergic reaction such as those listed at the start of this leaflet.

The above list includes very serious side effects. You may need urgent medical attention.

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

After using DBLTM Diazoxide Injection

Storage

DBLTMDiazoxide 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.

Product description

What it looks like

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

Ingredients

 $DBL^{\text{\tiny TM}}Diazoxide$ Injection contains diazoxide as the active ingredient.

It also contains:

- · sodium hydroxide
- water for injections

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

DBLTMDiazoxide Injection is supplied by:

Australian Sponsor:

Hospira Australia Pty Ltd ABN 58 097 064 330 Level 3 500 Collins Street Melbourne VIC 3000 Australia

New Zealand Sponsor:

Hospira NZ Limited 23 Haining Street Te Aro Wellington New Zealand

 $DBL^{\text{\tiny TM}}Diazoxide$ Injection is available in the following strength:

• 300 mg/20 mL amp AUST R 16377

This leaflet was prepared in November 2011.