Package leaflet: Information for the patient
DIAMOX® Powder for Solution for Injection
500mg/vial
(Acetazolamide)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT DIAMOX® IS AND WHAT IT IS USED FOR
DIAMOX® Powder for Solution for Injection 500mg/viaI belongs to a group of drugs called carbonic anhydrase inhibitors. DIAMOX® is used to treat the eye condition glaucoma, and also fluid retention and epilepsy.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN DIAMOX®

You should not be given DIAMOX® if:
• you are allergic to acetazolamide or any of the other ingredients of this medicine (listed in section 6).
• are you pregnant, breast feeding or trying for a baby.
• are you allergic to sulphonamides or sulphonamide derivatives.
• you have or have ever had severe liver disease (problems).
• you have or have ever had severe kidney problems.
• you have a particular type of glaucoma known as chronic non congestive angle closure glaucoma.
• you have reduced function of the adrenal glands - glands above the kidneys (also known as Addison's disease).
• you have low blood levels of sodium and/or potassium or high blood levels of chlorine.

Warnings and precautions
Talk to your doctor or nurse before you are given DIAMOX® if:
• you have liver problems.
• you have or ever had kidney problems such as kidney stones.
• you have trouble passing urine.
• you have lung problems such as chronic bronchitis or emphysema.
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• you have diabetes or impaired glucose tolerance.
• you have a history of generalised red, scaly rash (acute generalised exanthematous pustulosis [AGEP]) when treated with acetazolamide.

A small number of people being treated with anti-epileptics such as DIAMOX® have had thoughts of harming or killing themselves, if at any time you have these thoughts, immediately contact your doctor.

Talk to your doctor or nurse after you are given DIAMOX® if:
• you have muscle weakness.
• you have any allergic reaction (anaphylaxis)
• you have or had unusual skin rash.
• you are receiving treatment or a special diet for low levels of sodium or potassium or high levels of chlorine in your blood.

Other medicines and DIAMOX®
Tell your doctor or nurse if you are taking or have recently taken or might take any other medicines.
• aspirin (either prescribed or bought over-the-counter), as it may increase acidity in the blood and increase the risk of toxicity
• other medicines in the group called carbonic anhydrase inhibitors (medicines to treat the eye condition called glaucoma)
• medicines for your heart such as cardiac glycosides (e.g. digoxin)
• medicines to treat blood pressure
• medicines to thin your blood (e.g. warfarin)
• medicines to lower the sugar in your blood
• medicines for epilepsy (in particular, phenytoin, primidone or carbamazepine)
• drugs which interfere with folic acid, e.g. methotrexate, pyrimethamine or trimethoprim
• steroids such as prednisolone
• amphetamines (a stimulant), quinidine (treats an irregular heart beat), methenamine (prevents urine infections) or lithium (treats severe mental problems)
• sodium bicarbonate therapy (used to treat acidity)
• immunosuppressant cyclosporin (used to suppress the immune system)

Pregnancy and breast feeding:
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicines.

Pregnancy
Diamox Injection SHOULD NOT be taken if you are pregnant, think you are pregnant or are planning to become pregnant.

Breastfeeding
It may be taken when breast feeding but only on the advice of the doctor.

Driving and using machines
If DIAMOX® makes you feel drowsy or confused you should not drive or operate machinery.

DIAMOX® can occasionally cause short-sightedness, if this happens you should take care when driving and contact your doctor.

Diamox Injection contains sodium:
This medicine contains less than 1 mmol sodium (23mg) per dose, i.e. essentially "sodium-free".

3. HOW YOU ARE GIVEN DIAMOX®

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure

The recommended dose is:
Glaucoma:
Adults: The usual dosage is between 250-1000mg each day in separate doses.

Children: The usual dosage is between 125-750mg each day in separate doses.

Fluid retention (Congestive heart failure, drug-induced oedema): The usual dosage is 250-375mg once daily in the morning.

Fluid retention associated with pre-menstrual tension: The usual dosage is 125-375mg as a single dose.

Epilepsy:

Adults: The usual dosage for adults is 250-1000mg each day in separate doses.

Children: The usual dosage for children is 125-750mg each day in separate doses. The dose for infants is 125mg each day in separate doses. Some people may require less than the usual recommended dose, especially if they are also taking other tablets or medicines. Also, if you are an elderly person or you have kidney problems you may need less than the usual dose.

Your doctor will give DIAMOX® to you by injecting it into one of your veins (intravenous) or into one of your muscles (intramuscular). The medicine is firstly dissolved in water for injection to make a solution for injection. The dose you are to receive will depend on your condition.

If you have given more of DIAMOX
If you accidentally receive more than the required dose of DIAMOX® you may experience one or more of the symptoms mentioned in section 4. Remember, if you do experience any of these symptoms, tell your doctor so that the appropriate treatment can be given.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Diamox Injection can cause side effects, although not everybody gets them.

DIAMOX® may cause skin rashes including an increased sensitivity to sunlight, hypersensitivity reactions leading to itching, redness, fever, blistering or difficulty in breathing. If you experience

any of these symptoms or if you have pain in your joints, you should contact your doctor straight away. In severe cases shock and death have been reported.

DIAMOX® can affect the cells in your blood. This could mean that you are more likely to catch infections and that your blood may not clot properly. If you have a sore throat or fever or you notice bruises or tiny red or purple spots on your skin, you should contact your doctor immediately. If your muscles feel weak or you have fits, you should see your doctor immediately.

DIAMOX ® may affect some tests. If you visit a hospital or clinic for any medical tests you should tell your doctor concerned you are taking DIAMOX®. Most people do not get side effects when they receive DIAMOX®, but if you experience any of the symptoms described below or if you experience any symptoms not listed, please contact your doctor or pharmacist.

Not known: frequency cannot be estimated from the available data

- headache,
- diarrhoea,
- nausea,
- vomiting,
- loss of appetite,
- dizziness,
- flushing,
- thirst,
- a metallic taste in the mouth,
- a need to pass urine more often than normal,
- tiredness,
- irritability,
- excitement,
- lack of muscle control or coordination
- tingling or numbness in the fingers or toes. depression,
- a loss of interest in sex,
- ringing in the ears or impairment of hearing.
- shortsightedness may occur which subsides when the dosage is reduced or treatment is stopped. DIAMOX® can affect the liver and kidneys. If you have pain in your lower back, pain or burning when you pass urine, difficulty in passing urine or stop passing urine, blood in your urine, pale stools, or if your skin or eyes look slightly yellow, you should contact your doctor. You should also contact your doctor if your stools are black or tarry, or if you notice blood in your stools.
- low amount of electrolytes such as potassium and sodium in your blood
- bone thinning
- kidney stones
- high or low blood sugar levels
- growth retardation in children
- Contact a doctor immediately if you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). The frequency of this side effects is not known (cannot be estimated from the available data).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DIAMOX®
Keep this medicine out of the sight and reach of children.
Do not use this medicine after expiry date which is stated on the label and carton after EXP.
Do not store above 25°C.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What DIAMOX® contains
- The active substance is acetazolamide sodium.
Each vial of DIAMOX® Powder for Solution for Injection 500mg/vial contains acetazolamide sodium equivalent to 500mg acetazolamide as a powder for solution for injection.
- The other ingredients which are used to make DIAMOX® Powder for Solution for Injection 500mg/vial include sodium hydroxide and hydrochloric acid.

What DIAMOX® looks like and contents of the pack

DIAMOX® is a powder for injection which on reconstitution with 5ml of Water for Injections forms a solution for injection. DIAMOX® Powder for Solution for Injection 500mg/vial is supplied in boxes of 1 vial.

Marketing Authorisation Holder
Amdipharm Limited, Temple Chambers, 3 Burlington Road, Dublin 4, Ireland.

Manufacturer:
Mercury Pharmaceuticals Limited, Capital House, 85 King William Street, London EC4N 7BL, UK

Alternate Manufacturer:
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