

5. HOW TO STORE DIAMOX INJECTION

Keep out of the sight and reach of children.

Do not use after the expiry date. This date is printed on your pack. The Expiry date refers to last day of that month.

Do not store above 25°C

Any unused solution can be stored in a refrigerator for up to 24 hours but any solution not used within this time must be discarded.

For single use only.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Diamox Injection Contains:

The active substance is acetazolamide. Each vial contains 500mg acetazolamide.

The other ingredients are sodium hydroxide, hydrochloric acid and water for injection.

What Diamox Injection look like and contents of the pack:

Diamox Injection is a white powder, packed in glass vials with a rubber ring and aluminium seal. Before use, it is made into a solution, using at least 5ml water for injection.

Marketing Authorisation Holder and Manufacturer:

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MercuryPharma

PATIENT INFORMATION LEAFLET

Diamox® Sodium 500mg Powder for Solution for Injection

Acetazolamide

Read all of this leaflet carefully before you start taking this medicine. Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist. If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Diamox Sodium 500mg Powder for Solution for Injection. It will be referred to as Diamox Injection for ease of use hereafter.

In this leaflet:

1. What Diamox Injection is and what it is used for
2. Before you are given Diamox Injection
3. How you are given Diamox Injection
4. Possible side effects
5. How to store Diamox Injection
6. Further information

1. WHAT DIAMOX INJECTION IS AND WHAT IT IS USED FOR

Diamox Injection contains the active substance Acetazolamide. This belongs to a group of medicines known as carbonic anhydrase inhibitors.

Diamox Injection is used to treat:

- glaucoma (a condition of the eye), by reducing the pressure within the eye.
- Fluid retention
- Some forms of epilepsy ("fits"), in combination with other anti-epileptic drugs.

2. BEFORE YOU ARE GIVEN DIAMOX INJECTION

You should NOT be given Diamox Injection if:

- you know you are allergic to sulphonamides, sulphonamide derivatives including acetazolamide or to any of the ingredients in the medicine (listed in Section 6 at the end of this leaflet)
- you have or have ever had severe liver disease
- You have, or have ever had severe kidney problems
- you have a particular type of glaucoma known as chronic non congestive angle closure glaucoma (your doctor will be able to advise you)
- 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 (your doctor will advise you)

Speak to your doctor if any of the above applies to you.

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Take special care and speak to your doctor before taking Diamox Injection if:

- you have or have ever had kidney problems such as kidney stones
- you have lung problems such as chronic bronchitis or emphysema, which causes difficulty in breathing
- you have diabetes or problems with your blood sugar level
- You are over the age of 65

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.

Taking other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. The effects of any of these medicines may change, particularly if you are taking, or using, any of the following:

- medicines for your heart such as cardiac glycosides (e.g. digoxin)
- medicines to reduce blood pressure
- medicines to thin your blood (e.g. warfarin)
- medicines to lower the sugar in your blood
- medicines for epilepsy or fits (in particular, phenytoin, primidone or carbamazepine or topiramate)
- Drugs which interfere with folic acid, eg methotrexate, pyrimethamine, or trimethoprim
- steroids such as prednisolone
- aspirin and related medicines, eg salicylic acid or choline salicylate for mouth ulcers
- other drugs in the group of medicines called carbonic anhydrase inhibitors
- amphetamines (a stimulant), quinidine (treats an irregular heart beat), methenamine (prevents urine infections) or lithium (treats severe mental problems)
- sodium bicarbonate therapy
- ciclosporin (used to suppress the immune system)

Pregnancy and breast feeding:

Ask your doctor or pharmacist for advice before taking any medicines.

Diamox Injection SHOULD NOT be taken if you are pregnant, think you are pregnant or are planning to become pregnant. It may be taken when breast feeding but only on the advice of the doctor.

Driving and using machines:

If Diamox Injection makes you feel drowsy or confused you should not drive or operate machines. Diamox Injection can occasionally cause short-sightedness; if this happens and you feel that you can no longer drive safely, you should stop driving and contact your doctor.

Important information about some of the ingredients of Diamox Injection:

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

3. HOW YOU ARE GIVEN DIAMOX INJECTION

Diamox Injection is a white powder which firstly dissolved in water to make a solution for injection either into one of your veins (intravenous) or into one of your muscles (intramuscular).

The dose varies from person to person depending on their condition. Your doctor will decide on the most appropriate dose.

Before starting and during treatment your doctor will monitor your blood to check that treatment with Diamox Injection is suitable for you.

If you are given more Diamox Injection than you should:

As the injection will be administered by a doctor, it is unlikely that you will be given more than is necessary.

If you have any further questions on the use of this product ask your doctor.

4. POSSIBLE SIDE EFFECTS

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

All medicines can cause allergic reactions although serious allergic reactions are very rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

Extremely rarely, Diamox Injection 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.

Common side effects include:

- headache
- diarrhoea
- feeling or being sick, loss of appetite, thirst, or a metallic taste in the mouth
- dizziness, loss of full control of arms or legs
- looking flushed
- a need to pass urine more often than normal
- tiredness or irritability
- feeling over-excited
- a tingling or numbness in the fingers or toes, or coldness in the extremities

Other side effects include:

- depression
- drowsiness or confusion
- a loss of interest in sex
- ringing in the ears or difficulty in hearing
- temporary short-sightedness which subsides when the dosage is reduced or treatment is stopped.

Rare cases of skin rashes including an increased sensitivity to sunlight have been reported. If you experience any unusual skin rashes, inform your doctor.

Very rarely, Diamox Injection can affect the liver and kidneys. If you experience pain in your lower back, pain or burning when you pass urine, have difficulty in passing urine, or you stop passing urine, have 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.

If you are given Diamox Injection for a long time it can occasionally affect the amount of potassium, or sodium in your blood. Your doctor will probably take blood tests to check that this does not happen. You might also experience bone thinning or the risk of kidney stones with long-term therapy. High or low blood sugar levels may occasionally occur.

If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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