

PACKAGE LEAFLET: INFORMATION FOR THE USER

DIAMOX[®] 250MG TABLETS

(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. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. 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.

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1. WHAT DIAMOX TABLETS ARE AND WHAT THEY ARE USED FOR

DIAMOX 250mg Tablets (referred to as Diamox Tablets throughout this leaflet) contain the active substance Acetazolamide. This belongs to a group of medicines known as carbonic anhydrase inhibitors.

DIAMOX Tablets are used to treat:

- glaucoma (a condition of the eye), by reducing the pressure within the eye.
- abnormal retention of fluids (DIAMOX Tablets acts as a diuretic)
- epilepsy (fits or convulsions).

2. BEFORE YOU TAKE DIAMOX TABLETS

DO NOT take DIAMOX Tablets 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 severe liver 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 (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.

Take special care and speak to your doctor before taking DIAMOX Tablets if:

- you have or have ever had kidney problems such as kidney stones
- you have lung problems such as chronic bronchitis or emphysema, which cause difficulty in breathing
- you are over the age of 65.
- a small number of people being treated with anti-epileptics such as Acetazolamide have had thoughts of harming or killing themselves, if at any time you have these thoughts, immediately contact your doctor.

DIAMOX Tablets may affect some medical tests. If you visit a hospital or clinic for any medical tests, you should tell the doctor concerned that you are taking DIAMOX Tablets

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 (e.g. metformin, gliclazide)
- medicines for epilepsy or fits (in particular, phenytoin, primidone or carbamazepine or topiramate)
- Drugs which interfere with folic acid, e.g. methotrexate, pyrimethamine, or trimethoprim
- · steroids such as prednisolone
- · aspirin and related medicines, e.g. salicylic acid or choline salicylate for mouth ulcers
- other drugs in the group of medicines called carbonic anhydrase inhibitors (e.g. dorzolamide or brinzolamide which are also used to treat glaucoma)
- 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 high states of acid in your body)
- ciclosporin (used to suppress the immune system)

Pregnancy and breast feeding

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

DIAMOX Tablets 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 Tablets make you feel drowsy or confused you should not drive or operate machines. DIAMOX Tablets 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.

3. HOW TO TAKE DIAMOX TABLETS

- Always take the number of tablets your doctor has told you to take. This information will also be on the label.
- Diamox Tablets should be swallowed whole with a drink of water, just before or just after a meal. Do not chew or crush the tablets.
- The dose varies from person to person depending on their condition. Your doctor will decide on the most appropriate dose. If you are not sure how many tablets to take or when to take them, ask your doctor or pharmacist.

USUAL DOSES:

<u>Glaucoma:</u>

Adults: 250mg-1000mg (1-4 tablets) every 24 hours, in divided doses

Retention of fluid:

Adults: starting dose is 250-375mg (1-1.5 tablets) once daily in the morning. Your doctor will adjust the dose and tell you how often to take your dose.

Epilepsy:

Adults: 250-1000mg daily in divided doses

Children: the dose will depend on the bodyweight of the child, to be taken in divided doses. Dose should not be more than 750mg (3 tablets) per day.

• Before starting and during treatment your doctor may monitor your blood to check that treatment with DIAMOX Tablets is suitable for you.

If you take more DIAMOX Tablets than you should:

Get medical help immediately, either by calling your doctor or going to the nearest hospital casualty department. Take any remaining tablets and this leaflet with you so that the medical staff know exactly what you have taken

If you forget to take your DIAMOX Tablets

You should take it as soon as you remember. However, if this is within two hours of your next dose you should skip the missed tablets and carry on taking the rest of your tablets as usual.

DO NOT take a double dose of tablets to make up the missed dose.

If you have any further questions about these tablets, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DIAMOX Tablets 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 Tablets 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.

Very rarely, DIAMOX Tablets 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.

Common side effects are:

- 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
- Uncommon side effects are:
- 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.

If you take DIAMOX Tablets 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.

5. HOW TO STORE DIAMOX TABLETS

Do not store above 25°C. Store in the original pack or in containers which prevents the access of moisture.

Keep out of the reach and sight of children.

Do not use after the expiry date. This date is printed on your pack.

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.

REMEMBER

This medicine is for you. Only a doctor can prescribe it for you. Never give this medicine to someone else; it could harm them, even if their symptoms seem the same as yours.

6. FURTHER INFORMATION

What DIAMOX Tablets Contain

The active substance is Acetazolamide. Each tablet contains 250mg acetazolamide.

The other ingredients are dicalcium phosphate, corn starch, magnesium stearate, sodium starch glycolate, povidone.

What DIAMOX Tablets look like and contents of the pack

DIAMOX Tablets are white, round, convex tablets with "FW 147" on one side and scored in quarters on the other. They usually come amber glass bottles with metal screw on caps or plastic bottles with plastic caps, containing 112 or 1000 tablets.

Marketing Authorisation Holder: Goldshield Pharmaceuticals Ltd, NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey, CR0 0XT, UK Manufacturer: Custom Pharmaceuticals Limited, Conway Street, Hove, East Sussex, BN3 3LW, UK

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