Package leaflet: Information for the user
Diamox SR® 250mg Prolonged-release Capsules
acetazolamide

Read all of this leaflet carefully before you start taking 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 pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Diamox SR 250mg Prolonged-release Capsules. It will be referred to as Diamox SR Capsules for ease of use hereafter.

What is in this leaflet:

1. What Diamox SR Capsules are and what they are used for
Diamox SR 250mg Prolonged-release Capsules contain the active substance Acetazolamide. This belongs to a group of medicines known as carbonic anhydrase inhibitors.
Diamox SR Capsules are used to treat, **glaucoma** (a condition of the eye), by reducing the pressure within the eye.

2. What you need to know before you take Diamox SR Capsule
Do not take Diamox SR Capsules:
- if you are allergic to acetazolamide or to any of the other ingredients of this medicine (listed in Section 6)
- if you have severe liver problems
- if you have or have ever had severe kidney problems
- if you have a particular type of glaucoma known as chronic non congestive angle closure
- glaucoma (your doctor will be able to advise you)
- if you have reduced function of the adrenal glands - glands above the kidneys - (also known as Addison's disease)
- if you have low blood levels of sodium and/or potassium or high blood levels of chlorine (your doctor will advise you)
- if the person this medicine has been prescribed for is under the age of 12.

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Diamox SR Capsules

- if you have or have ever had kidney problems such as kidney stones
- if you experienced lung or breathing problems such as fluid in the lungs or chronic bronchitis or emphysema, which cause difficulty in breathing following acetazolamide intake in the past.
- if you have diabetes or problems with your blood sugar level
- if you are over the age of 65
- if 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.

If you develop shortness of breath or difficulty breathing after taking Diamox SR Capsules, seek medical attention immediately (see also section 4).

A decrease in vision or eye pain could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion or choroidal detachment). This can happen within hours of taking Diamox SR Capsules. Talk to your doctor promptly if you experience these symptoms.

Children and adolescents

Diamox SR Capsules should not be used in children.

Other medicines and Diamox SR Capsules
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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)
- anti-diabetic medicines to lower the sugar in your blood (e.g. metformin)
- 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 (used to treat raised pressure in your eye(s))
- 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 conditions where there is excess acid in your body)
- ciclosporin (used after transplants to suppress the immune system).

Diamox SR Capsules 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 SR Capsules.

Pregnancy and breast feeding
Diamox SR Capsules SHOULD NOT be taken if you are pregnant, think you may be pregnant or are planning to have a baby.

It may be taken when breast feeding, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines:
If Diamox SR Capsules make you feel drowsy or confused you should not drive or operate machines. Diamox SR Capsules 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.

Diamox SR Capsules contains sunset yellow FCF (E110)
This medicine contains the ingredient sunset yellow FCF (E110) which may cause allergic reactions.

Information on Sodium content:
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Diamox SR Capsules

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

- The usual recommended dosage is 1 or 2 capsules a day taken just before or just after a meal.
- Diamox SR Capsules should be swallowed whole with a drink of water. Do not chew or crush the capsules.
- The dose varies from person to person depending on their condition. If you are not sure how many capsules to take or when to take them, ask your pharmacist.
- Before starting and during treatment your doctor will monitor your blood to check that treatment with Diamox SR Capsules is suitable for you.

Use in Children and adolescents
Diamox SR Capsules are not recommended for use in children.

If you take more Diamox SR Capsules than you should
Get medical help immediately, either by calling your doctor or going to the nearest hospital casualty department. Take any remaining capsules and this leaflet with you so that the medical staff knows exactly what you have taken.

If you forget to take your Diamox SR Capsules

You should take it as soon as you remember. However, if this is within 2 hours of your next dose you should skip the missed capsule and carry on taking the rest of your capsules as usual.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine 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. Tell your doctor immediately if you notice any of the following side effects:
- fever, severe chills, sore throat or mouth ulcers
- bruises or tiny red or purple spots on your skin
- a severe condition of the skin that may affect the mouth and other parts of the body. This may progress to a severe skin reaction which starts with painful red areas, then large blisters and ends up with peeling of layers of skin, mouth, nose, eyes or genitals. This may be accompanied by fever and chills, aching muscles and generally feeling unwell
- weakness or paralysis, and reduced muscle tone
- you have fits
- pain or burning when you pass urine, have difficulty in passing urine or you stop passing urine, or have blood in your urine
- your stools are black or tarry, or if you notice blood in your stools
- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the
- skin and eyes, and dark colour urine
- decrease in the number of red blood cells. tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- decrease in white blood cells
- Softening of bones when used along with drugs used to treat fits/ convulsions
- kidney problems.
- Decrease in vision or pain in your eyes due to accumulation of fluid in the vascular layer of the eye (choroidal effusion or choroidal detachment) (Frequency 'not known').
- If you develop shortness of breath or difficulty breathing. These can be symptoms of accumulation of fluid in the lungs (pulmonary oedema). The frequency of this side effect cannot be estimated from the available data (not known).

Tell your doctor as soon as possible if you notice any of the following side effects:
- pain in your lower back
- pale stools.
- your skin or eyes look slightly yellow.

You may also experience the following:
Common: (may affect up to 1 in 10 people)
- 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
- low blood sugar
- a tingling or numbness in the fingers or toes, or coldness in the extremities

Uncommon: (may affect up to 1 in 100 people)
- 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.
- low Platelet count,
- decrease in cells production responsible for providing immunity and
- low potassium levels

Rare: (may affect up to 1 in 1,000 people)
- skin rashes including an increased sensitivity to sunlight

If you take Diamox SR Capsules 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.

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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diamox SR Capsules
Keep this medicine out of the sight and reach of children.
Store below 30 °C
Store in the original package in order to protect from light and moisture.
Do not use this medicine after the expiry date which is stated on the carton after EXP.The Expiry date refers to last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer use. 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. Contents of the pack and other information:

What Diamox SR Capsules Contains:

The active substance is acetazolamide. Each capsule contains 250mg acetazolamide.
The other ingredients are microcrystalline cellulose (E460), sodium lauryl sulphate, purified water, ethyl cellulose, hydroxypropyl methylcellulose (E464), mineral oil, Pigment Blend PB-230005 Orange [hydroxy propyl cellulose, titanium dioxide and FD&C Yellow #6/Sunset Yellow FCF aluminium lake (15-18% grade), Talc and FD&C Yellow #6/Sunset yellow FCF aluminium lake (38-42% grade)].
Capsule shell contains gelatin, titanium dioxide (E171), yellow iron oxide (E172) and erythrosine (E127).

What Diamox SR Capsules look like and contents of the pack:

Diamox SR capsules have a clear body and orange cap, and are printed with 'GS 250' in black. They usually come in blister packs of 28 or 30 capsules, although the capsule may also be available in bottles of 28, 100 or 500. Not all pack sizes may be marketed.

Marketing Authorization Holder:

Mercury Pharmaceuticals Ltd., Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

Manufacturer:

Mercury Pharmaceuticals Ltd., Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

Alternate Manufacture:
Rottendorf Pharma GmbH, Ostenfelder Strasse 51-61, D-59320 Ennigerloh, Germany

This leaflet was last revised in October 2024.

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