Package leaflet: Information for the user

Diamox® SR 250mg Modified Release Hard 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness 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 Modified Release Hard Capsules. It will be referred to as Diamox SR 250mg capsules for ease hereafter.

What is in this leaflet

1. What Diamox SR 250mg capsules are and what they are used for

Diamox SR 250mg capsules contain the active substance acetazolamide. This belongs to a group of medicines known as carbonic anhydrase inhibitors.

Diamox SR 250mg capsules are used to treat glaucoma (a condition of the eye), by reducing the pressure within the eye.
It is indicated in adults and older people.

2. What you need to know before you take Diamox SR 250mg capsules

Do not take Diamox SR 250mg capsules
- If you are allergic to acetazolamide or any of the other ingredients of this medicine (listed in section 6)
- if you have severe kidney or liver problems
- if you are suffering from adrenal glands disorders
- if you have high blood levels of chlorine
- if you have low blood levels of sodium and/or potassium
- if you have a particular type of glaucoma known as chronic non congestive angle closure glaucoma
- if you are allergic to sulphonamides and its derivatives

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Diamox SR 250mg capsules:
- if you have or ever had suicidal thoughts.
- if you have sensation of tingling, tickling, pricking and burning in the extremities
- if you feel abnormal sleep during the day
- if you have or ever had any kind of blood disorders
- if you have been treated with sulphonamides, sulphonamides derivatives or acetazolamide before
- if you have or ever had kidney problems such as kidney stones or trouble passing urine
- if you experienced lung or breathing problems (fluid in the lungs) following acetazolamide intake in the past.
- if you are over the age of 65
- if you have diabetes or problems with your blood sugar level
- if you are pregnant, breast feeding or trying for a baby

If you develop shortness of breath or difficulty breathing after taking Diamox SR 250mg capsules, seek medical attention immediately (see also section 4).

Acetazolamide may affect some medical tests.

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 250mg capsules. Talk to your doctor promptly if you experience these symptoms.

Children and adolescents
Diamox SR 250mg capsules is not intended for administration in children.

Other medicines and Diamox SR 250 mg Capsules
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines such as:
- medicines that interfere with folic acid, as the effect may be increased
- medicines to reduce the sugar levels in your blood, as the effect may be increased or decreased
- medicines to thin your blood, as the effect may be increased
- aspirin, as it may increase the acidity in the blood or alter the normal activity of the nervous system
- cardiac glycosides (medicines to treat heart failure), as the dose may need to be adjusted
- medicines to increase blood pressure, as the dose may need to be adjusted
- anticonvulsants (medicines to treat epilepsy or fits) such as phenytoin, primidone or carbamazepine, as the effect may be increased or decreased and may lead to severe cases of osteomalacia (softening of the bones)
- other medicines in the group called carbonic anhydrase inhibitors (medicines to treat the eye condition called glaucoma), as the effect may be increased
- amphetamines (medicines used as stimulants), as the effect may be increased
- quinidine (medicine to treat irregular heart beat), as the effect may be increased
- methenamine (medicine to treat urinary infections), as the elimination from the body may be affected
- lithium (medicine to treat severe mental problems), as the effect may be decreased
- sodium bicarbonate (medicine used to treat acidity), as the risk of kidney stones may be increased

- cyclosporine (medicine used to suppress the immune system), as the effect may be increased

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask yourdoctor or pharmacist for advice before taking this medicine.

Diamox SR 250 mg Capsules should not be taken if you are pregnant, or planning to become pregnant, especially in first trimester since there is a very small chance that your baby may be affected.
It may be taken when breast feeding but only on the advice of the doctor.

Driving and using machines
You shouldn't drive or operate machines while on Diamox SR 250mg capsules. Diamox SR 250mg capsules make you feel drowsy, tired or confused and can occasionally cause distant objects to appear blurred.

Diamox SR 250mg capsules contains sunset yellow FCF (E110)
This product contains the excipient 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 250mg 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 dose of Diamox SR 250mg capsules varies from person to person depending on your condition. Some people may need smaller doses, especially if they are also taking other capsules or medicines. Also, if you are an elderly person you may need less than the usual dose.

The recommended dose is 250mg once or two times a day.

Method of administration

- capsules should be swallowed whole with a glass of water.
- do not chew or crush the capsule.

If you take more Diamox SR 250mg capsules than you should
If you have taken an overdose of Diamox SR 250mg capsules (that is more capsules than the physician has told you to) get medical help **immediately**, either by calling your physician or going to the nearest hospital casualty department. Take this leaflet, the pack or any capsules with you, if you can.

If you forget to take Diamox SR 250mg capsules

If you do forget to take a capsule 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 stop taking Diamox SR 250mg capsules

Do not stop taking Diamox SR 250mg capsules until your doctor tells you to do so**.**

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them**.**

If you are worried about side effects, ask your doctor. It is important that you know what can happen, so that you can take action if Diamox SR 250mg capsules does have a side effect.

If any of the following happen, stop taking Diamox SR 250mg capsules and tell your doctor immediately:

Rare (may affect up to 1 in 10,000 people):

- if you have pale stools or if your skin or eyes look slightly yellow.

Not known (frequency cannot be estimated from the available data):

- hypersensitivity reactions: itching, redness, fever, blistering or difficulty in breathing or pain in your joints.
- if you have a sore throat, fever, or you notice unusual rash, bruises or tiny red or purple spots on your skin.
- if your muscles feel weak.
- if you have fits.
- 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.
- if your stools are black or tarry or if you notice blood in your stools.
- 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).

Contact a doctor immediately 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).

Other side effects:

Rare (may affect up to 1 in 10,000 people):

- increased sensitivity to sunlight

Not known (frequency cannot be estimated from the available data):

- headache
- diarrhoea
- feeling or being sick
- loss of appetite
- dizziness

- drowsiness
- flushing
- thirst
- metallic taste in the mouth
- need to pass urine more often than normal
- tiredness
- irritability
- excitement
- confusion
- lack of movements coordination
- tingling or numbness in the fingers or toes
- coldness in the extremities
- depression
- loss of interest in sex
- ringing in the ears or difficulty in hearing
- temporary short-sightedness
- decrease in the number of blood cells (you are more likely to catch infections and that your blood may not clot properly)
- low or high levels of sugar in the blood
- acidemia (excessive levels of acid in your blood)
- abnormal levels of electrolytes in the blood
- abnormal results when testing the liver function

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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diamox SR 250mg capsules

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month. Do not store above 30°C.
For the blisters: Store in the original package, in order to protect from moisture. Keep the blisters in the outer carton, in order to protect from light.
Keep this medicine out of the sight and reach of children.
If your physician decides to stop your medicine you should return any capsules that are left to your pharmacist for disposal.
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 SR 250 mg capsules contains

- The active substance is acetazolamide. Each capsules contains 250 mg acetazolamide.
- The other ingredients are Microcrystalline Cellulose, Sodium laurilsulfate, Purified Water, Ethyl cellulose, andHydroxypropylmethyl cellulose, Light Liquid Paraffin, Pigment Blend PB-230005 Orange [hydroxyl 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 250mg capsules looks like and contents of the pack

Size 1, hard shell capsules with clear body and orange coloured cap with imprint "GS 250" in black ink containing orange spherical pellets.

Pack Size:
DIAMOX SR 250mg Capsules are licensed for blister pack of 28 and 30. (Not all pack sizes may be marketed)
DIAMOX SR 250mg Capsules is currently supplied in blister pack of 30 capsules.

Marketing Authorisation Holder

Amdipharm Limited,
Temple Chambers, 3 Burlington Road,
Dublin 4, Ireland

Manufacturer
Mercury Pharmaceuticals Ltd.,
Capital House, 85 King William Street,
London, EC4N 7BL, United Kingdom

Alternate Manufacturer
Rottendorf Pharma GmbH
Ostenfelder Strasse 51-61,
59320 Ennigerloh, Germany

The leaflet was last revised in October 2024.

Mercury Pharma Group Ltd. is licensed to use the registered trade mark Diamox.