

Patient leaflet: Information for the user

EYTAZOX® 250 MG 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 signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What Eytazox is and what it is used for
2. What you need to know before you take Eytazox
3. How to take Eytazox
4. Possible side effects
5. How to store Eytazox
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1. What Eytazox is and what it is used for

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

Eytazox is 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 Eytazox

Do not take Eytazox if:

- You know you are allergic to sulfonamides, sulfonamide derivatives including acetazolamide or to any of the ingredients in the capsules (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)
- The person this medicine has been prescribed for is under the age of 12.

Children and adolescents

Eytazox should not be used in children.

Warnings and precautions

Talk to your doctor or pharmacist before taking Eytazox 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 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 Acetazolamide have had thoughts of harming or killing themselves, **if at any time you have these thoughts, immediately contact your doctor.**

Other medicines and Eytazox

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking 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).

Eytazox 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 Eytazox Prolonged-Release Capsules.

If you are unsure of the types of medicines you are taking, ask your doctor or pharmacist.

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

Driving and using machines

If Eytazox make you feel drowsy or confused you should not drive or operate machines. Eytazox 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.

Eytazox contains sunset yellow FCF (E110)

This may cause allergic reactions.

3. How to take Eytazox

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

Eytazox should be swallowed whole with a drink of water. Do not chew or crush the capsules.

The recommended dose is:

- The usual recommended dosage is 1 or 2 capsules a day taken just before or just after a meal.
- 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 Eytazox Prolonged-Release Capsules is suitable for you.

Use in children and adolescents

Eytazox Prolonged-Release Capsules are not recommended for use in children.

If you take more Eytazox 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 know exactly what you have taken.

If you forget to take Eytazox

Take the dose as soon as you remember to take it and then continue on as before. 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 have 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.

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 effect is not known (cannot be estimated from the available data).

Tell your doctor immediately if you notice any of the following side effects:

- Reduction in the number of white blood cells and 'platelets', these effects may result in unusual bruising or bleeding or increased risk of infection, 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
- Liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark colour urine
- Anaemia or bone marrow depression (a condition in which there is a decrease in the number of red blood cells. Symptoms include tiredness, headaches, being short of breath when exercising, dizziness and looking pale).

Tell your doctor as soon as possible if you notice any of the following side effects:

- Pain in your lower back
- Pale stools.

You may also experience the following:

- 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
- 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.

If you take Eytazox 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 above side effects are troublesome or last more than a few days or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the yellow card scheme at 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 Eytazox

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date that is stated on the carton after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions. 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 Eytazox contains

- The active substance is Acetazolamide
- The other ingredients are hypromellose, microcrystalline cellulose, purified talc, colloidal anhydrous silica, ethylcellulose, light liquid paraffin and opaspray orange (hydroxypropylcellulose, titanium dioxide [E171], talc, sunset yellow FCF [E110]). The capsule shell contains gelatin, titanium dioxide (E171), iron oxide yellow (E172) and iron oxide red (E172).

What Eytazox looks like and contents of the pack

Eytazox Prolonged-Release Capsules are hard gelatin capsules with a clear body and orange cap, printed with 'AM250' in black ink, containing round orange pellets. Eytazox Prolonged-Release Capsules are available in boxes of 30 capsules.

Not all pack sizes may be marketed.

Marketing authorisation holder:

Auden Mckenzie (Pharma Division) Ltd.,
Whiddon Valley, Barnstaple, North Devon,
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Manufacturer:

Actavis UK Limited
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Auden Mckenzie

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