Package leaflet: Information for the user

Acetazolamide Mercury Pharma 250mg Tablets

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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Acetazolamide 250mg Tablets are and what they are used for
2. What you need to know before you take Acetazolamide 250mg Tablets
3. How to take Acetazolamide 250mg Tablets
4. Possible side effects
5. How to store Acetazolamide 250mg Tablets
6. Contents of the pack and other information

1. What Acetazolamide 250mg Tablets are and what they are used for
Acetazolamide 250mg Tablets (referred to as Acetazolamide 250mg Tablets throughout this leaflet) contain the active substance Acetazolamide. This belongs to a group of medicines known as carbonic anhydrase inhibitors.
Acetazolamide 250mg Tablets are used to treat:
• glaucoma (a condition of the eye), by reducing the pressure within the eye.
• abnormal retention of fluids (Acetazolamide 250mg Tablets acts as a diuretic)
• epilepsy (fits or convulsions).

2. What you need to know before you take Acetazolamide 250mg Tablets
Do not take Acetazolamide 250mg 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)
• 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).
Speak to your doctor if any of the above applies to you.

Warnings and precautions
Talk to your doctor or pharmacist before taking Acetazolamide 250mg Tablets

• if you have or have ever had kidney problems such as kidney stones
• if you have lung problems such as chronic bronchitis or emphysema, which cause difficulty in breathing
• if 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.

Acetazolamide 250mg 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 Acetazolamide 250mg Tablets.

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

Other medicines and Acetazolamide 250mg Tablets

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)
• 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, 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 (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

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.

<u>Pregnancy</u>

Acetazolamide 250mg Tablets SHOULD NOT be taken if you are pregnant, think you are pregnant or are planning to become pregnant.

<u>Breast feeding</u>

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

Driving and using machines
If Acetazolamide 250mg Tablets make you feel drowsy or confused you should not drive or operate machines. Acetazolamide 250mg 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.

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 Acetazolamide 250mg Tablets
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
• This information will also be on the label.
• Acetazolamide 250mg 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.

The recommended dose is
Glaucoma:
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 Acetazolamide 250mg Tablets is suitable for you.

If you take more Acetazolamide 250mg 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 Acetazolamide 250mg 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 tablet and carry on taking the rest of your tablets 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.

Acetazolamide 250mg 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.

Acetazolamide 250mg 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.

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

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 Acetazolamide 250mg 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.

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).

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.

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 Acetazolamide 250mg Tablets

Do not store above 25°C. Store in the original pack or in containers which prevents the access of moisture.
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on 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 Acetazolamide 250mg 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 Acetazolamide 250mg Tablets look like and contents of the pack:
Acetazolamide 250mg Tablets are white, circular shallow biconvex tablets with quarter breakline on one side and engraved “FW” and “147” on other side. They usually come in amber glass bottles with metal screw on caps or plastic bottles with plastic caps, containing 112 tablets.
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Marketing Authorisation Holder: Mercury Pharmaceuticals Ltd., Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

Manufacturer:
Custom Pharmaceuticals Limited,

Conway Street, Hove,
East Sussex, BN3 3LW, UK

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SAINT QUENTIN FALLAVIER, 38070, France

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