PATIENT INFORMATION LEAFLET

Acetazolamide 500mg Powder for solution for injection

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 nurse.
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Acetazolamide Sodium 500mg Powder for Solution for Injection. It will be referred to as Acetazolamide Injection for ease of use hereafter.

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

1. WHAT ACETAZOLAMIDE INJECTION IS AND WHAT IT IS USED FOR

Acetazolamide injection contains the active substance Acetazolamide. This belongs to a group of medicines known as carbonic anhydrase inhibitors.
Acetazolamide injection is used to treat:
• glaucoma (a condition of the eye), by reducing the pressure within the eye.
• fluid retention
• some forms of epilepsy (“fits”), in combination with other anti-epileptic drugs.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN ACETAZOLAMIDE INJECTION

You should NOT be given Acetazolamide injection if:
• you are allergic to acetazolamide or to any of the ingredients in the medicine (listed in section 6.)
• you are allergic to sulphonamides or sulphonamide derivatives
• you have or have ever had severe liver disease
• 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.

Warnings and precautions
Talk to your doctor or nurse before are given Acetazolamide injection if:
• you have or have ever had kidney problems such as kidney stones
• you have trouble passing urine.
• you experienced lung or breathing problems such as fluid in the lungs or chronic bronchitis or emphysema, which causes difficulty in breathing following acetazolamide intake in the past.
• you have diabetes or problems with your blood sugar level
• you have a history of generalised red, scaly rash (acute generalised exanthematous pustulosis [AGEP]) when treated with acetazolamide.

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

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.

Talk to your doctor or nurse after you are given Acetazolamide injection if:
• you have muscle weakness.
• you have any allergic reaction (anaphylaxis)
• you have or had unusual skin rash.
• you are receiving treatment or a special diet for low levels of sodium or potassium.

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 Injection. Talk to your doctor promptly if you experience these symptoms.

Other medicines and Acetazolamide injection
Tell your doctor or nurse if you are taking or 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
• 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
• amphetamines (a stimulant), quinidine (treats an irregular heartbeat), methenamine (prevents urine infections) or lithium (treats severe mental problems)
• sodium bicarbonate therapy (used to treat acidity)
• ciclosporin (used to suppress the immune system)

Pregnancy, breast feeding and fertility
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 any medicines.

Pregnancy
Acetazolamide injection SHOULD NOT be taken if you are pregnant, think you are pregnant or are planning to become pregnant.

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

Driving and using machines
If Acetazolamide injection makes you feel drowsy or confused, you should not drive or operate machines. Acetazolamide injection 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.

Acetazolamide injection contains sodium
This medicine contains less than 1 mmol sodium (23mg) per dose, i.e. essentially “sodium-free”.

3. HOW YOU ARE GIVEN ACETAZOLAMIDE INJECTION

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

The recommended dose is:

i) **Glaucoma**:

Adults: 250 - 1000mg per 24 hours, usually in separate doses for amounts over 250mg daily.

ii) **Fluid retention (Congestive heart-failure, drug-induced oedema):** The usual dose is 250 - 375mg once daily in the morning.

Fluid retention associated with pre-menstrual tension: The usual dosage is 125-375mg as a single dose.

iii) **Epilepsy**

Adults: The usual dosage is 250 - 1000mg daily in separate doses.

Use in Children: The usual dose is 8 - 30mg/kg in daily separate doses and should not to exceed 750mg/day.

Acetazolamide injection is a white powder which firstly dissolved in water to make a solution for injection either into one of your veins (intravenous) or into one of your muscles (intramuscular). The dose varies from person to person depending on their condition. Your doctor will decide on the most appropriate dose. Before, starting and during treatment your doctor will monitor your blood to check that treatment with Acetazolamide injection is suitable for you.

If you are given more Acetazolamide injection than you should:
As the injection will be administered by a doctor, it is unlikely that you will be given more than is necessary.
If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Acetazolamide injection 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:

- skin rashes including an increased sensitivity to sunlight
- Acetazolamide injection 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.
- sore throat or fever
- bruises or tiny red or purple spots on your skin,
- muscles feel weak or you have fits
- 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, stools are black or tarry, or blood in your stools.
- 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).

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).

You may also experience the following:
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
• glucose in the urine or cloudy urine
• 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
• low amount of potassium, or sodium in your blood.
• kidney stones.
• high or low blood sugar levels.
• 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).

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 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 ACETAZOLAMIDE INJECTION

Keep out of the reach and sight of children.
Do not use this medicine after the expiry date which is stated on the label and carton. The Expiry date refers to last day of that month.
Do not store above 25°C
Any unused solution can be stored in a refrigerator for up to 24 hours but any unused solution after this period must be discarded.
For single use only.
Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away of medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Acetazolamide injection Contains
The active substance is acetazolamide. Each vial contains 500mg acetazolamide.
The other ingredients are sodium hydroxide, hydrochloric acid and water for injections.

What Acetazolamide injection look like and contents of the pack
Acetazolamide injection is a white powder, packed in glass vials with a rubber ring and aluminium seal. Before use, it is made into a solution, using at least 5ml water for injection.

Marketing Authorisation Holder and Manufacturer:
Mercury Pharmaceuticals Ltd,

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