Diamox® Sodium 500 mg Powder for Solution for Injection

2879
19.11.24[9]

(acetazolamide)

PATIENT INFORMATION LEAFLET

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.

Your medicine is available using the above name but will be referred to as Diamox Injection throughout this leaflet.

What is in this leaflet

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

Diamox Injection contains the active substance acetazolamide. This belongs to a group of medicines known as carbonic anhydrase inhibitors.

Diamox 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 DIAMOX INJECTION

You should NOT be given Diamox 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, sulphonamide derivatives
- you have or have ever had severe liver disease (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).

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

Warnings and precautions

Talk to your doctor or nurse before you are given Diamox 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 Diamox Injection, seek medical attention immediately (see also section 4).

A small number of people being treated with anti-epileptics such as Diamox Injection 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 Diamox 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 Diamox Injection. Talk to your doctor promptly if you experience these symptoms.

Other medicines and Diamox 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
Diamox 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 Diamox Injection makes you feel drowsy or confused, you should not drive or operate machines. Diamox 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.

Diamox Injection contains sodium:

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

3. HOW YOU ARE GIVEN DIAMOX 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 – 1000 mg per 24 hours, usually in separate doses for amounts over 250 mg daily.

ii) Fluid retention (Congestive heart-failure, drug-induced oedema):

The usual dose is 250 – 375 mg 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 – 1000 mg daily in separate doses.

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

Diamox Injection is a white powder which will be 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 Diamox Injection is suitable for you.

If you are given more Diamox 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, Diamox 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
- Diamox 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
- bone thinning or the risk of 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 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 INJECTION
Keep out of the sight and reach of children.

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.

Do not use after the expiry date. This date is printed on your pack. The Expiry date refers to last day of that month.

For single use only.

If the powder becomes discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Diamox Injection contains:
The active substance is acetazolamide.
Each vial contains 500 mg acetazolamide (as acetazolamide sodium).
The other ingredients are sodium hydroxide and hydrochloric acid for pH adjustment.

What Diamox Injection looks like and contents of the pack:
Diamox Injection is a white powder, packed in a transparent glass vial with a grey rubber stopper, aluminium ring seal and blue plastic plug. Before use, it is made into a solution, using at least 5 ml water for injection.
Each carton contains 1 vial.

Manufacturer and product licence holder
Manufactured by Mercury Pharmaceuticals Ltd, Capital House, 85 King William Street, London EC4N 7BNL, United Kingdom.
Procured from within the EU by product licence holder Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex HA1 1XD. Repackaged by Servipharm Ltd.

POM | PL 20636/2879

Leaflet revision and issue date (Ref) 19.11.24[9]

Blind or partially sighted?
Is this leaflet hard to see or read?
Call 020 8423 2111 to obtain the leaflet in a format suitable for you.

HEALTH PROFESSIONALS' USER LEAFLET

2879
19.11.24[H-9]

1. NAME OF THE MEDICINAL PRODUCT

Diamox Sodium 500 mg Powder for solution for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains acetazolamide 500 mg

Excipient(s) with known effect

For full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

White powder for solution for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Acetazolamide is an enzyme inhibitor which acts specifically on carbonic anhydrase. It is indicated in the treatment of:

i) Glaucoma: Diamox injection is useful in glaucoma (chronic simple (open angle) glaucoma, secondary glaucoma and perioperatively in acute angle closure glaucoma where delay of surgery is desired in order to lower intraocular pressure) because it acts on inflow, decreasing the amount of aqueous secretion.

ii) Abnormal retention of fluids: Diamox injection is a diuretic whose effect is due to the effect on the reversible hydration of carbon dioxide and dehydration of carbonic acid reaction in the kidney. The result is a renal loss of HCO^{3-} ion which carries out sodium, water and potassium. Diamox injection can be used in conjunction with other diuretics when effects on several segments of the nephron are desirable in the treatment of fluid retaining states.

iii) Epilepsy: In conjunction with other anticonvulsants best results with Diamox injection have been seen in petit mal in children. Good results, however, have been seen in patients, both children and adults, with other types of seizures such as grand mal, mixed seizure patterns, myoclonic jerk patterns, etc.

4.2 Posology and method of administration

Posology

i) Glaucoma (simple acute congestive and secondary):
Adults: 250-1000 mg per 24 hours, usually in divided doses for amounts over 250 mg daily.

ii) Abnormal retention of fluid: Congestive heart-failure, drug-induced oedema.
Adults: For diuresis, the starting dose is usually 250-375 mg once daily in the morning. If, after an initial response, the patient fails to continue to lose oedema fluid, do not increase the dose but allow for kidney recovery by omitting a day. Best results are often obtained on a regime of 250-375 mg daily for two days, rest a day, and repeat or merely giving Diamox injection every other day. The use of Diamox injection does not eliminate the need for other therapy, e.g. digitalis, bed rest and salt restriction in congestive heart failure and proper supplementation with elements such as potassium in drug-induced oedema. For cases of fluid retention associated with pre-menstrual tension, a daily dose (single) of 125-375 mg is suggested.

iii) Epilepsy
Adults: 250-1000 mg daily in divided doses.
Children: 8-30 mg/kg in daily divided doses and not to exceed 750 mg/day.
The change from other medication to Diamox should be gradual.
Elderly: Diamox injection should only be used with particular caution in elderly patients or those with potential obstruction in the urinary tract or with disorders rendering their electrolyte balance precarious or with liver dysfunction.
For reconstitution please refer to section 6.6 below

Method of Administration:

Intravenous or intramuscular injection. The direct intravenous route is preferred as intramuscular use is limited by the alkaline pH of the solution.

4.3 Contraindications

Hypersensitivity to acetazolamide or to any of the excipients listed in section 6.1.

Diamox injection should not be used in patients hypersensitive to sulphonamides.

Diamox injection is contraindicated in situations in which sodium and/or potassium blood levels are depressed, in cases of marked kidney and liver dysfunction, suprarenal gland failure and hyper-chloremic acidosis.

Diamox injection should not be used in patients with hepatic cirrhosis as this may increase the risk of hepatic encephalopathy.

Long-term administration of Diamox injection is contra-indicated in patients with chronic non-congestive angle-closure glaucoma since it may permit organic closure of the angle to occur while the worsening glaucoma is masked by lower intraocular pressure.

4.4 Special warnings and precautions for use

Suicidal ideation and behaviour have been reported in patients treated with antiepileptic agents in several indications. A meta-analysis of randomised placebo controlled trials of anti-epileptic drugs has also shown a small increased risk of suicidal ideation and behaviour. The mechanism of this risk is not known and the available data do not exclude the possibility of an increased risk for Diamox injection. Therefore patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge.

Increasing the dose does not increase the diuresis and may increase the incidence of drowsiness and/or paraesthesia.

Increasing the dose often results in a decrease in diuresis. Under certain circumstances, however, very large doses have been given in conjunction with other diuretics in order to secure diuresis in complete refractory failure.

When Diamox injection is prescribed for long-term therapy, special precautions are advisable. The patient should be cautioned to report any unusual skin rash. Periodic blood cell counts and electrolyte levels are recommended. Fatalities have occurred, although rarely, due to severe reactions to sulphonamides including acetazolamide, such as Steven-Johnson syndrome and toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anaemia and other blood dyscrasias and anaphylaxis. A precipitous drop in formed blood cell elements or the appearance of toxic skin manifestations should call for immediate cessation of Diamox injection therapy.

Acetazolamide treatment may cause electrolyte imbalances, including hyponatraemia and transient hypokalaemia, as well as metabolic acidosis. Therefore, periodic monitoring of serum electrolytes is recommended.

Particular caution is recommended in patients with conditions that are associated with, or predispose to, electrolyte and acid/base imbalances, such as patients with impaired renal function (including elderly patients), pulmonary obstruction or emphysema patients with diabetes mellitus and patients with impaired alveolar ventilation. Severe metabolic acidosis has been reported in patients with normal renal function during treatment with acetazolamide and salicylates.

Both increases and decreases in blood glucose levels have been described in patients treated with acetazolamide. This should be taken into consideration in patients with impaired glucose tolerance or diabetes mellitus.

In patients with a past history of renal calculi, benefit should be balanced against the risks of precipitating further calculi.

The pH of parenteral acetazolamide is 9.1. Care should be taken during intravenous administration of alkaline preparations to avoid extravasation and possible development of skin necrosis.

The occurrence at the treatment initiation of a feverish generalized erythema associated with pustula may be a symptom of acute generalised exanthematous pustulosis (AGEP) (See section 4.8). In case of AGEP diagnosis, acetazolamide should be discontinued and any subsequent administration of acetazolamide contraindicated.

Non-cardiogenic pulmonary oedema

Severe cases of non-cardiogenic pulmonary oedema have been reported after taking acetazolamide, also after a single dose (see section 4.8). Non-cardiogenic pulmonary oedema typically developed within minutes to hours after acetazolamide intake. Symptoms included dyspnoea, hypoxia, and respiratory insufficiency. If non-cardiogenic pulmonary oedema is suspected, acetazolamide should be withdrawn, and supportive treatment should be given. Acetazolamide should not be administered to patients who previously experienced non-cardiogenic pulmonary oedema following acetazolamide intake. Cases of choroidal effusion/detachment have been reported after the use of acetazolamide. Symptoms include acute onset of decreased visual acuity or ocular pain and can occur within hours after initiation of acetazolamide treatment. If choroidal effusion/detachment is suspected, acetazolamide should be discontinued as rapidly as possible.

4.5 Interactions with other medicinal products and other forms of interaction

Acetazolamide is a sulphonamide derivative. Sulphonamides may potentiate the effects of folic acid antagonists. Possible potentiation of the effects of folic acid antagonists, hypoglycaemics and oral anti-coagulants.

Concurrent administration of acetazolamide and aspirin may result in severe acidosis and increase central nervous system toxicity. Adjustments of dose may be required when Diamox injection is given with cardiac glycosides or hypertensive agents. When given concomitantly acetazolamide modifies the metabolism of phenytoin leading to increased serum levels of phenytoin. Severe osteomalacia has been noted in a few patients taking acetazolamide in combination with other anticonvulsants. There have been isolated reports of reduced primidone and increased carbamazepine serum levels with concurrent administration of acetazolamide.

Because of possible additive effects with other carbonic anhydrase inhibitors, concomitant use is not advisable.

Both increases and decreases in blood glucose levels have been described in patients with acetazolamide. This should be taken into consideration in patients treated with anti-diabetic agents.

By increasing the pH of renal tubular urine, acetazolamide reduces the urinary excretion of amphetamine and quinidine and so may enhance the magnitude and duration of the effect of amphetamines and enhance the effect of quinidine.

By increasing the pH of urine, acetazolamide may prevent the urinary excretion of methenamine compounds.

Acetazolamide increases lithium excretion due to impaired re-absorption of lithium in the proximal tubule. The effect of lithium carbonate may be decreased. The use of concurrent sodium bicarbonate therapy enhances the risk of renal calculus formation in patients taking acetazolamide.

When given concomitantly, acetazolamide may elevate cyclosporine blood levels. Caution is advised when administrating acetazolamide in patients receiving cyclosporine.

4.6 Fertility, pregnancy and lactation

Pregnancy

Acetazolamide has been reported to be teratogenic and embryotoxic in rats, mice, hamsters and rabbits at oral or parenteral doses in excess of ten times those recommended in human beings. Although there is no evidence of these effects in human beings, there are no adequate and well-controlled studies in pregnant women. Therefore, Diamox injection should not be used in pregnancy, especially during the first trimester.

Breast-feeding

Acetazolamide has been detected in low levels in the milk of lactating women who have taken Diamox injection. Although it is unlikely that this will lead to any harmful effects in the infant, extreme caution should be exercised when Diamox injection is administered to lactating women.

4.7 Effects on Ability to Drive and Use Machines

Increasing the dose does not increase the diuresis and may increase the incidence of drowsiness and/or paraesthesia. Less commonly, fatigue, dizziness and ataxia have been reported. Disorientation has been observed in a few patients with oedema due to hepatic cirrhosis. Such cases should be under close supervision. Transient myopia has been reported.
These conditions invariably subside upon diminution or discontinuance of the medication.

4.8 Undesirable Effects

The following adverse reactions are classified by system organ class and ranked under heading of frequency using the following convention:
Not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reactions
Blood and lymphatic system disorders	Not known	Agranulocytosis, thrombocytopenia, thrombocytopenic purpura, leukopenia, aplastic anaemia, bone marrow depression and pancytopenia.[1]
Immune system disorders	Not known	Anaphylactic reaction
Metabolism and nutrition disorders	Not known	Metabolic acidosis and electrolyte imbalance.[2] Decreased appetite, hyponatraemia, hyperglycaemia, hypoglycaemia
Psychiatric disorders	Not known	Loss of libido, irritability, confusional state and depression.[3]
Nervous system disorders	Not known	Paraesthesia, particularly a tingling feeling in the extremities, headache, dizziness, ataxia, somnolence and dysgeusia. Flaccid paralysis and seizures.
Eye disorders	Not known	Transient myopia[4], choroidal effusion, choroidal detachment
Ear and labyrinth disorders	Not known	Impaired hearing and tinnitus.
Vascular disorders	Not known	Flushing
Respiratory, thoracic and mediastinal disorders	Not known	Non-cardiogenic pulmonary oedema
Gastrointestinal disorders	Not known	Nausea, vomiting, diarrhoea and melaena.
Hepatobiliary disorders	Not known	Hepatic necrosis, hepatic function abnormal, and hepatitis or cholestatic jaundice.
Skin and subcutaneous tissue disorders	Not known	Urticaria, rash (including erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis). Photosensitivity.[3] Acute generalised exanthematous pustulosis (AGEP)
Renal and urinary disorders	Not known	Haematuria, polyuria, glycosuria crystalluria, nephrolithiasis renal colic and renal lesions.[1]
General disorders and administration site conditions	Not known	Flushing, fatigue, thirst, Pyrexia.[1]

[1] Acetazolamide is a sulphonamide derivative and therefore some side effects similar to those caused by sulphonamides have occasionally been reported.
[2] During long-term therapy, metabolic acidosis and electrolyte imbalance may occasionally occur. This can usually be corrected by the administration of bicarbonate.
[3] Adverse reactions during short-term therapy are usually non-serious.
[4] The condition invariably subsides upon diminution or discontinuation of the medication.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

4.9 Overdose

Management

No specific antidote. Supportive measures with correction of electrolyte and fluid balance. Force fluids.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Carbonic anhydrase inhibitors.
ATC Code: S01EC01.

Mechanism of action

Acetazolamide is an inhibitor of carbonic anhydrase. By inhibiting the reaction catalysed by this enzyme in the renal tubules, acetazolamide increases the excretion of bicarbonate and of cations, chiefly sodium and potassium, and so promotes alkaline diuresis.

Pharmacodynamic effects

Continuous administration of acetazolamide is associated with metabolic acidosis and resultant loss of diuretic activity. Therefore the effectiveness of Diamox injection in diuresis diminishes with continuous use.
By inhibiting carbonic anhydrase in the eye acetazolamide decreases intra-ocular pressure and is therefore useful in the treatment of glaucoma.

5.2 Pharmacokinetic Properties

Distribution

It is tightly bound to carbonic anhydrase and accumulates in tissues containing this enzyme, particularly red blood cells and the renal cortex. It is also bound to plasma proteins.

Elimination

Acetazolamide has been estimated to have a plasma half-life of about 4 hours. It is excreted unchanged in the urine, renal clearance being enhanced in the alkaline urine.

5.3 Preclinical Safety Data

Nothing of note to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)

6.2 Incompatibilities

None.

6.3 Shelf Life

60 months.

6.4 Special Precautions for Storage

Do not store above 25°C.

6.5 Nature and Contents of Container

Diamox Injection is a white powder, packed in a transparent glass vial with a grey rubber stopper, aluminum ring seal and blue plastic plug. Before use, it is made into a solution, using at least 5ml water for injection.
Each carton contains 1 vial.

6.6 Special precautions for disposal and other handling

Reconstitute each vial of Diamox injection with at least 5 ml of water for injection prior to use. The reconstituted solution is clear and colourless and does not contain an antimicrobial preservative. Any unused solution can be stored in a refrigerator for up to 24 hours but any unused solution after this period must be discarded.
The direct intravenous route of administration is preferred. Intramuscular injection may be employed but is painful due to the alkaline pH of the solution.

7. PRODUCT LICENCE HOLDER

Procured from within the EU by product licence holder Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex HA1 1XD.

8. PRODUCT LICENCE NUMBER

PL 20636/2879

Leaflet revision and issue date (Ref): 19.11.24[H-9]

Acetazolamide 500 mg Powder for Solution for Injection

2879
19.11.24[9]

(acetazolamide)

PATIENT INFORMATION LEAFLET

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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.

Your medicine is available using the above name but will be referred to as Acetazolamide Injection throughout this leaflet.

What is in this leaflet

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, sulphonamide derivatives
- you have or have ever had severe liver disease (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).

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

Warnings and precautions

Talk to your doctor or nurse before you 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 Injection 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 (23 mg) 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 – 1000 mg per 24 hours, usually in separate doses for amounts over 250 mg daily.

ii) Fluid retention (Congestive heart-failure, drug-induced oedema):

The usual dose is 250 – 375 mg 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 – 1000 mg daily in separate doses.

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

Acetazolamide Injection is a white powder which will be 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
- bone thinning or the risk of 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 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 INJECTION
Keep out of the sight and reach of children.

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.

Do not use after the expiry date. This date is printed on your pack. The Expiry date refers to last day of that month.

For single use only.

If the powder becomes discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. 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 500 mg acetazolamide (as acetazolamide sodium).
The other ingredients are sodium hydroxide and hydrochloric acid for pH adjustment.

What Acetazolamide Injection looks like and contents of the pack:
Acetazolamide Injection is a white powder, packed in a transparent glass vial with a grey rubber stopper, aluminium ring seal and blue plastic plug. Before use, it is made into a solution, using at least 5 ml water for injection. Each carton contains 1 vial.

Manufacturer and product licence holder
Manufactured by Mercury Pharmaceuticals Ltd, Capital House, 85 King William Street, London EC4N 7BNL, United Kingdom.
Procured from within the EU by product licence holder Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex HA1 1XD. Repackaged by Servipharm Ltd.

POM | PL 20636/2879

Leaflet revision and issue date (Ref) 19.11.24[9]

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Call 020 8423 2111 to obtain the leaflet in a format suitable for you.

HEALTH PROFESSIONALS' USER LEAFLET

1. NAME OF THE MEDICINAL PRODUCT

Acetazolamide 500 mg Powder for solution for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains acetazolamide 500 mg

Excipient(s) with known effect

For full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

White powder for solution for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Acetazolamide is an enzyme inhibitor which acts specifically on carbonic anhydrase. It is indicated in the treatment of:

i) Glaucoma: Acetazolamide injection is useful in glaucoma (chronic simple (open angle) glaucoma, secondary glaucoma and perioperatively in acute angle closure glaucoma where delay of surgery is desired in order to lower intraocular pressure) because it acts on inflow, decreasing the amount of aqueous secretion.

ii) Abnormal retention of fluids: Acetazolamide injection is a diuretic whose effect is due to the effect on the reversible hydration of carbon dioxide and dehydration of carbonic acid reaction in the kidney. The result is a renal loss of HCO^{3-} ion which carries out sodium, water and potassium.
Acetazolamide injection can be used in conjunction with other diuretics when effects on several segments of the nephron are desirable in the treatment of fluid retaining states.

iii) Epilepsy: In conjunction with other anticonvulsants best results with Acetazolamide injection have been seen in petit mal in children. Good results, however, have been seen in patients, both children and adults, with other types of seizures such as grand mal, mixed seizure patterns, myoclonic jerk patterns, etc.

4.2 Posology and method of administration

Posology

i) Glaucoma (simple acute congestive and secondary):
Adults: 250-1000 mg per 24 hours, usually in divided doses for amounts over 250 mg daily.

ii) Abnormal retention of fluid: Congestive heart-failure, drug-induced oedema.
Adults: For diuresis, the starting dose is usually 250-375 mg once daily in the morning. If, after an initial response, the patient fails to continue to lose oedema fluid, do not increase the dose but allow for kidney recovery by omitting a day. Best results are often obtained on a regime of 250-375 mg daily for two days, rest a day, and repeat or merely giving Acetazolamide injection every other day. The use of Acetazolamide injection does not eliminate the need for other therapy, e.g. digitalis, bed rest and salt restriction in congestive heart failure and proper supplementation with elements such as potassium in drug-induced oedema. For cases of fluid retention associated with pre-menstrual tension, a daily dose (single) of 125-375 mg is suggested.

iii) Epilepsy
Adults: 250-1000 mg daily in divided doses.
Children: 8-30 mg/kg in daily divided doses and not to exceed 750 mg/day.
The change from other medication to Acetazolamide should be gradual.
Elderly: Acetazolamide injection should only be used with particular caution in elderly patients or those with potential obstruction in the urinary tract or with disorders rendering their electrolyte balance precarious or with liver dysfunction.
For reconstitution please refer to section 6.6 below

Method of Administration:

Intravenous or intramuscular injection. The direct intravenous route is preferred as intramuscular use is limited by the alkaline pH of the solution.

4.3 Contraindications

Hypersensitivity to acetazolamide or to any of the excipients listed in section 6.1.

Acetazolamide injection should not be used in patients hypersensitive to sulphonamides.

Acetazolamide injection is contraindicated in situations in which sodium and/or potassium blood levels are depressed, in cases of marked kidney and liver dysfunction, suprarenal gland failure and hyper-chloremic acidosis.

Acetazolamide injection should not be used in patients with hepatic cirrhosis as this may increase the risk of hepatic encephalopathy.

Long-term administration of Acetazolamide injection is contra-indicated in patients with chronic non-congestive angle-closure glaucoma since it may permit organic closure of the angle to occur while the worsening glaucoma is masked by lower intraocular pressure.

4.4 Special warnings and precautions for use

Suicidal ideation and behaviour have been reported in patients treated with antiepileptic agents in several indications. A meta-analysis of randomised placebo controlled trials of anti-epileptic drugs has also shown a small increased risk of suicidal ideation and behaviour. The mechanism of this risk is not known and the available data do not exclude the possibility of an increased risk for Acetazolamide injection. Therefore patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge.

Increasing the dose does not increase the diuresis and may increase the incidence of drowsiness and/or paraesthesia.

Increasing the dose often results in a decrease in diuresis. Under certain circumstances, however, very large doses have been given in conjunction with other diuretics in order to secure diuresis in complete refractory failure.

When Acetazolamide injection is prescribed for long-term therapy, special precautions are advisable. The patient should be cautioned to report any unusual skin rash. Periodic blood cell counts and electrolyte levels are recommended. Fatalities have occurred, although rarely, due to severe reactions to sulphonamides including acetazolamide, such as Steven-Johnson syndrome and toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anaemia and other blood dyscrasias and anaphylaxis. A precipitous drop in formed blood cell elements or the appearance of toxic skin manifestations should call for immediate cessation of Acetazolamide injection therapy.

Acetazolamide treatment may cause electrolyte imbalances, including hyponatraemia and transient hypokalaemia, as well as metabolic acidosis. Therefore, periodic monitoring of serum electrolytes is recommended. Particular caution is recommended in patients with conditions that are associated with, or predispose to, electrolyte and acid/base imbalances, such as patients with impaired renal function (including elderly patients), pulmonary obstruction or emphysema patients with diabetes mellitus and patients with impaired alveolar ventilation. Severe metabolic acidosis has been reported in patients with normal renal function during treatment with acetazolamide and salicylates.

Both increases and decreases in blood glucose levels have been described in patients treated with acetazolamide. This should be taken into consideration in patients with impaired glucose tolerance or diabetes mellitus.

In patients with a past history of renal calculi, benefit should be balanced against the risks of precipitating further calculi.

The pH of parenteral acetazolamide is 9.1. Care should be taken during intravenous administration of alkaline preparations to avoid extravasation and possible development of skin necrosis.

The occurrence at the treatment initiation of a feverish generalized erythema associated with pustula may be a symptom of acute generalised exanthematous pustulosis (AGEP) (See section 4.8). In case of AGEP diagnosis, acetazolamide should be discontinued and any subsequent administration of acetazolamide contraindicated.

Non-cardiogenic pulmonary oedema

Severe cases of non-cardiogenic pulmonary oedema have been reported after taking acetazolamide, also after a single dose (see section 4.8). Non-cardiogenic pulmonary oedema typically developed within minutes to hours after acetazolamide intake. Symptoms included dyspnoea, hypoxia, and respiratory insufficiency. If non-cardiogenic pulmonary oedema is suspected, acetazolamide should be withdrawn, and supportive treatment should be given. Acetazolamide should not be administered to patients who previously experienced non-cardiogenic pulmonary oedema following acetazolamide intake. Cases of choroidal effusion/detachment have been reported after the use of acetazolamide. Symptoms include acute onset of decreased visual acuity or ocular pain and can occur within hours after initiation of acetazolamide treatment. If choroidal effusion/detachment is suspected, acetazolamide should be discontinued as rapidly as possible.

4.5 Interactions with other medicinal products and other forms of interaction

Acetazolamide is a sulphonamide derivative. Sulphonamides may potentiate the effects of folic acid antagonists. Possible potentiation of the effects of folic acid antagonists, hypoglycaemics and oral anti-coagulants.

Concurrent administration of acetazolamide and aspirin may result in severe acidosis and increase central nervous system toxicity. Adjustments of dose may be required when Acetazolamide injection is given with cardiac glycosides or hypertensive agents. When given concomitantly acetazolamide modifies the metabolism of phenytoin leading to increased serum levels of phenytoin. Severe osteomalacia has been noted in a few patients taking acetazolamide in combination with other anticonvulsants. There have been isolated reports of reduced primidone and increased carbamazepine serum levels with concurrent administration of acetazolamide.

Because of possible additive effects with other carbonic anhydrase inhibitors, concomitant use is not advisable.

Both increases and decreases in blood glucose levels have been described in patients with acetazolamide. This should be taken into consideration in patients treated with anti-diabetic agents.

By increasing the pH of renal tubular urine, acetazolamide reduces the urinary excretion of amphetamine and quinidine and so may enhance the magnitude and duration of the effect of amphetamines and enhance the effect of quinidine.

By increasing the pH of urine, acetazolamide may prevent the urinary excretion of methenamine compounds.

Acetazolamide increases lithium excretion due to impaired re-absorption of

lithium in the proximal tubule. The effect of lithium carbonate may be decreased. The use of concurrent sodium bicarbonate therapy enhances the risk of renal calculus formation in patients taking acetazolamide.
When given concomitantly, acetazolamide may elevate cyclosporine blood levels. Caution is advised when administrating acetazolamide in patients receiving cyclosporine.

4.6 Fertility, pregnancy and lactation

Pregnancy

Acetazolamide has been reported to be teratogenic and embryotoxic in rats, mice, hamsters and rabbits at oral or parenteral doses in excess of ten times those recommended in human beings. Although there is no evidence of these effects in human beings, there are no adequate and well-controlled studies in pregnant women. Therefore, Acetazolamide injection should not be used in pregnancy, especially during the first trimester.

Breast-feeding

Acetazolamide has been detected in low levels in the milk of lactating women who have taken Acetazolamide injection. Although it is unlikely that this will lead to any harmful effects in the infant, extreme caution should be exercised when Acetazolamide injection is administered to lactating women.

4.7 Effects on Ability to Drive and Use Machines

Increasing the dose does not increase the diuresis and may increase the incidence of drowsiness and/or paraesthesia. Less commonly, fatigue, dizziness and ataxia have been reported. Disorientation has been observed in a few patients with oedema due to hepatic cirrhosis. Such cases should be under close supervision. Transient myopia has been reported.
These conditions invariably subside upon diminution or discontinuance of the medication.

4.8 Undesirable Effects

The following adverse reactions are classified by system organ class and ranked under heading of frequency using the following convention:
Not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reactions
Blood and lymphatic system disorders	Not known	Agranulocytosis, thrombocytopenia, thrombocytopenic purpura, leukopenia, aplastic anaemia, bone marrow depression and pancytopenia.[1]
Immune system disorders	Not known	Anaphylactic reaction
Metabolism and nutrition disorders	Not known	Metabolic acidosis and electrolyte imbalance.[2] Decreased appetite, hyponatraemia, hyperglycaemia, hypoglycaemia
Psychiatric disorders	Not known	Loss of libido, irritability, confusional state and depression.[3]
Nervous system disorders	Not known	Paraesthesia, particularly a tingling feeling in the extremities, headache, dizziness, ataxia, somnolence and dysgeusia. Flaccid paralysis and seizures.
Eye disorders	Not known	Transient myopia[4], choroidal effusion, choroidal detachment
Ear and labyrinth disorders	Not known	Impaired hearing and tinnitus.
Vascular disorders	Not known	Flushing
Respiratory, thoracic and mediastinal disorders	Not known	Non-cardiogenic pulmonary oedema
Gastrointestinal disorders	Not known	Nausea, vomiting, diarrhoea and melaena.
Hepatobiliary disorders	Not known	Hepatic necrosis, hepatic function abnormal, and hepatitis or cholestatic jaundice.
Skin and subcutaneous tissue disorders	Not known	Urticaria, rash (including erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis). Photosensitivity.[3] Acute generalised exanthematous pustulosis (AGEP)
Renal and urinary disorders	Not known	Haematuria, polyuria, glycosuria crystalluria, nephrolithiasis renal colic and renal lesions.[1]
General disorders and administration site conditions	Not known	Flushing, fatigue, thirst, Pyrexia.[1]

[1] Acetazolamide is a sulphonamide derivative and therefore some side effects similar to those caused by sulphonamides have occasionally been reported.
[2] During long-term therapy, metabolic acidosis and electrolyte imbalance may occasionally occur. This can usually be corrected by the administration of bicarbonate.
[3] Adverse reactions during short-term therapy are usually non-serious.
[4] The condition invariably subsides upon diminution or discontinuation of the medication.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

4.9 Overdose

Management

No specific antidote. Supportive measures with correction of electrolyte and fluid balance. Force fluids.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Carbonic anhydrase inhibitors.
ATC Code: S01EC01.

Mechanism of action

Acetazolamide is an inhibitor of carbonic anhydrase. By inhibiting the reaction catalysed by this enzyme in the renal tubules, acetazolamide increases the excretion of bicarbonate and of cations, chiefly sodium and potassium, and so promotes alkaline diuresis.

Pharmacodynamic effects

Continuous administration of acetazolamide is associated with metabolic acidosis and resultant loss of diuretic activity. Therefore the effectiveness of Acetazolamide injection in diuresis diminishes with continuous use.
By inhibiting carbonic anhydrase in the eye acetazolamide decreases intra-ocular pressure and is therefore useful in the treatment of glaucoma.

5.2 Pharmacokinetic Properties

Distribution

It is tightly bound to carbonic anhydrase and accumulates in tissues containing this enzyme, particularly red blood cells and the renal cortex. It is also bound to plasma proteins.

Elimination

Acetazolamide has been estimated to have a plasma half-life of about 4 hours. It is excreted unchanged in the urine, renal clearance being enhanced in the alkaline urine.

5.3 Preclinical Safety Data

Nothing of note to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)

6.2 Incompatibilities

None.

6.3 Shelf Life

60 months.

6.4 Special Precautions for Storage

Do not store above 25°C.

6.5 Nature and Contents of Container

Acetazolamide Injection is a white powder, packed in a transparent glass vial with a grey rubber stopper, aluminum ring seal and blue plastic plug. Before use, it is made into a solution, using at least 5ml water for injection. Each carton contains 1 vial.

6.6 Special precautions for disposal and other handling

Reconstitute each vial of Acetazolamide injection with at least 5 ml of water for injection prior to use. The reconstituted solution is clear and colourless and does not contain an antimicrobial preservative. Any unused solution can be stored in a refrigerator for up to 24 hours but any unused solution after this period must be discarded.
The direct intravenous route of administration is preferred. Intramuscular injection may be employed but is painful due to the alkaline pH of the solution.

7. PRODUCT LICENCE HOLDER

Procured from within the EU by product licence holder Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex HA1 1XD.

8. PRODUCT LICENCE NUMBER

PL 20636/2879

Leaflet revision and issue date (Ref): 19.11.24[H-9]