# MOXAID 250MG TABLETS
(acetazolamide)
PL 12762/0220
UKPAR

## TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lay Summary</td>
<td>2</td>
</tr>
<tr>
<td>Scientific discussion</td>
<td>3</td>
</tr>
<tr>
<td>Steps taken for assessment</td>
<td>11</td>
</tr>
<tr>
<td>Steps taken after authorisation – summary</td>
<td></td>
</tr>
<tr>
<td>Summary of Product Characteristics</td>
<td>12</td>
</tr>
<tr>
<td>Product Information Leaflet</td>
<td>17</td>
</tr>
<tr>
<td>Labelling</td>
<td>18</td>
</tr>
</tbody>
</table>
LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Goldshield Pharmaceuticals Limited a Marketing Authorisation (licence) for the medicinal product Moxaid 250mg Tablets (PL 12762/0220) on 19 October 2011. This is a prescription-only medicine (POM) used to treat:

- glaucoma (a condition of the eye), by reducing the pressure within the eye.
- abnormal retention of fluids (Moxaid 250mg Tablets acts as a diuretic)
- epilepsy (fits or convulsions).

Moxaid 250mg Tablets contain the active ingredient acetazolamide, which belongs to a group of medicines known as carbonic anhydrase inhibitors.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of using Moxaid 250mg Tablets outweigh the risks and a Marketing Authorisation was granted.
MOXAID 250 MG TABLETS
(acetazolamide)
PL 12762/0220

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

Introduction ................................................. Page 4
Pharmaceutical assessment .......................... Page 5
Non-clinical assessment ............................... Page 8
Clinical assessment ....................................... Page 9
Overall conclusions and risk assessment ........ Page 10
INTRODUCTION

The MHRA granted a Marketing Authorisation for the medicinal product Moxaid 250mg Tablets (PL 12762/0220) to Goldshield Pharmaceuticals Limited on 19 October 2011. The product is available as a prescription-only medicine (POM) and is indicated in the treatment of:

i) Glaucoma: Moxaid 250mg Tablets are useful in the treatment of 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 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 renal loss of HC03- ion which carries out sodium, water and potassium. Moxaid 250mg Tablets 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 Moxaid 250mg Tablets 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.

The application was submitted as an abridged application according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Diamox 250mg Tablets, which was originally granted a product licence of right to Cyanamid of Great Britain Limited on 12 February 1990. This licence then underwent a change of ownership to Goldshield Pharmaceuticals Limited (PL 12762/0147) on 12 December 2003.

The active ingredient, 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. By inhibiting carbonic anhydrase in the eye, acetazolamide decreases intra-ocular pressure and is therefore useful in the treatment of glaucoma.

No new data were submitted nor were they necessary for this simple application, as the data are identical to those of the previously granted cross-reference product.
PHARMACEUTICAL ASSESSMENT

Licence No: PL 12762/0220
Proprietary Name: Moxaid 250mg Tablets
Active: Acetazolamide
Company Name: Goldshield Pharmaceuticals Limited
E.C. Article: Article 10c of Directive 2001/83/EC
Legal Status: POM

1. INTRODUCTION
This is an abridged application Moxaid 250mg Tablets submitted under Article 10c of Directive 2001/83/EC, as amended. The proposed Marketing Authorisation Holder is Goldshield Pharmaceuticals Limited, NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey, CR0 0XT, United Kingdom,

The application cross-refers to Diamox 250mg Tablets (PL 12762/0147), which is currently authorised to Goldshield Pharmaceuticals Limited after a change in authorisation holder on 12 December 2003.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 Name(s)
The proposed name of the product is Moxaid 250mg Tablets. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
Each tablet contains 250 mg of the active ingredient, acetazolamide. The tablets are packaged in polypropylene bottles with polypropylene child resistant screw caps. These are packed into cardboard cartons with Patient Information Leaflets, in a pack size of 112 tablets.

The proposed shelf-life (48 months) and storage conditions (“Do not store above 25°C. Store in the original pack in order to protect from light and moisture ”) are consistent with the details registered for the cross-reference product.

2.3 Legal status
On approval, the product will be available as a prescription-only medicine (POM).

2.4 Marketing Authorisation Holder/Contact Persons/Company
Goldshield Pharmaceuticals Limited, NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey, CR0 0XT, United Kingdom.

The Qualified Person (QP) responsible for pharmacovigilance is stated and his CV is included.
2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in-line with the details registered for the cross-reference product.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
None of the excipients contain materials of animal or human origin. This is consistent with the cross-reference product.

2.11 Bioequivalence
No bioequivalence data are required to support this informed consent application, as the proposed product is manufactured to the same formula and utilising the same process as the reference product Diamox 250mg Tablets (PL 12762/0147).

3. EXPERT REPORTS
The applicant cross-references to the data for Diamox 250mg Tablets, to which it claims to be identical. This is acceptable.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The proposed Summary of Product Characteristics is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING
PIL
The patient information leaflet has been prepared in-line with the details registered for the cross-reference product.

Goldshield Pharmaceuticals Limited has previously submitted results of consultations with target patient groups (‘user testing’), in accordance with Article 59 of Council Directive 2001/83/EC, for the reference product Diamox 250mg Tablets (PL 12762/0147). The
results indicate that the leaflet is well-structured and organised, easy to understand, and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

As the leaflets for Diamox 250mg Tablets (PL 1272/0147) and this product are considered the same, no further user testing of the leaflet for this product is necessary.

**Carton and bottle label**
The proposed artwork is consistent with the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation, the applicant has also included the name of the product in Braille on the outer packaging.

7. **CONCLUSION**
The data submitted with the application are acceptable. The grant of a Marketing Authorisation is recommended.
NON-CLINICAL ASSESSMENT

As this is an abridged application submitted under Article 10c, of Directive 2001/83/EC as amended, no new non-clinical data have been supplied and none are required.

The grant of a Marketing Authorisation is recommended.
CLINICAL ASSESSMENT

As this is an abridged application submitted under Article 10c, of Directive 2001/83/EC as amended, no new clinical data have been supplied and none are required.

The grant of a Marketing Authorisation is recommended.
OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY
The data for this application are consistent with those previously assessed for the cross-reference product and as such have been judged to be satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for an application of this type.

EFFICACY
This application is identical to a previously granted application for Diamox 250mg Tablets (PL 1272/0147). No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE
The SmPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

BENEFIT/RISK ASSESSMENT
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. Extensive clinical experience with acetazolamide is considered to have demonstrated the therapeutic value of the product. The benefit/risk is, therefore, considered to be positive.
MOXAID 250 MG TABLETS
(acetazolamide)
PL 12762/0220

STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Marketing Authorisation application on 27 February 2006.
2. Following standard checks and communication with the applicant the MHRA considered the application valid on 11 May 2006.
5. The application was granted on 19 October 2011.
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
MOXAID 250mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each capsule contains 250 mg acetazolamide

Excipient(s): For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Tablet.

Round, convex, white tablets engraved with “FW 147” on one side and scored in quarters on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
MOXAID Tablets are for oral administration.

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

i) Glaucoma: MOXAID Tablets are useful in the treatment of 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 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 renal loss of HC03- ion which carries out sodium, water and potassium. MOXAID Tablets can be used in conjunction with other diuretics when effects on several segments of the nepbron are desirable in the treatment of fluid retaining states.

iii) Epilepsy: In conjunction with other anticonvulsants best results with MOXAID Tablets 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

i) Glaucoma (simple acute congestive and secondary):
Adults: 250 - 1,000mg (1-4 tablets) per 24 hours, usually in divided doses for amounts over 250mg daily.

ii) Abnormal retention of fluid: Congestive heart failure, drug-induced oedema.
Adults: For diuresis, the starting dose is usually 250 - 375mg (1-1½ tablets) 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 - 375mg (1-1½ tablets) daily for two days, rest a day, and repeat, or merely giving the MOXAID every other day. The use of MOXAID Tablets does not eliminate the need for other therapy, eg. 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 - 375mg is suggested.

iii) Epilepsy:
Adults: 250 - 1,000mg daily in divided doses.
Children: 8-30mg/kg in daily divided doses and not to exceed 750mg/day.
The change from other medication to MOXAID Tablets should be gradual.

Elderly: MOXAID Tablets 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.

4.3 Contraindications
Acetazolamide is contra-indicated in situations in which sodium and/or potassium blood levels are depressed, in cases of marked kidney and liver disease or dysfunction, suprarenal gland failure, and hyperchloremic acidosis. MOXAID Tablets should not be used in patients with hepatic cirrhosis as this may increase the risk of hepatic encephalopathy.

Long-term administration of MOXAID Tablets 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 lowered intraocular pressure.

MOXAID Tablets should not be used in patients hypersensitive to sulphonamides.

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 antiepileptic 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.

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 MOXAID Tablets are 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. A precipitous drop in formed blood cell elements or the appearance of toxic skin manifestations should call for immediate cessation of MOXAID Tablets therapy.

In patients with pulmonary obstruction or emphysema where alveolar ventilation may be impaired, MOXAID Tablets may aggravate acidosis and should be used with caution.

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

4.5 Interaction 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 may occur. Concurrent administration of acetazolamide and aspirin may result in severe acidosis and increase central nervous system toxicity. Adjustment of dose may be required when MOXAID Tablets are 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, concomitant use with other carbonic anhydrase inhibitors is not advisable.

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

Ciclosporin: Acetazolamide may elevate ciclosporin levels.

Methenamine: Acetazolamide may prevent the urinary antiseptic effect of methenamine.

Lithium: Acetazolamide increases lithium excretion and the blood lithium levels may be decreased.

Sodium bicarbonate: Acetazolamide and sodium bicarbonate used concurrently increases the risk of renal calculus formation.

4.6 Fertility, Pregnancy and lactation

Use in 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, MOXAID should not be used in pregnancy, especially during the first trimester.

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

Adverse reactions during short-term therapy are usually non-serious. Those effects which have been noted include: paraesthesia, particularly a “tingling” feeling in the extremities; some loss of appetite; taste disturbance, polyuria, flushing, thirst, headache, dizziness, fatigue, irritability, depression, reduced libido and occasional instances of drowsiness and confusion. Rarely, photosensitivity has been reported.

During long-term therapy, metabolic acidosis and electrolyte imbalance may occasionally occur. This can usually be corrected by the administration of bicarbonate.

Transient myopia has been reported. This condition invariably subsides upon diminution or withdrawal of the medication.

Gastro-intestinal disturbances such as nausea, vomiting and diarrhoea.

Acetazolamide is a sulphonamide derivative and therefore some side-effects similar to those caused by sulphonamides have occasionally been reported. These include fever, agranulocytosis, thrombocytopenia, thrombocytic purpura, leukopenia, and aplastic anaemia, bone marrow depression, pancytopenia, rash (including erythema multiforme, Stevens-Johnson Syndrome, toxic epidermal necrolysis), anaphylaxis, crystalluria, calculus formation, renal and ureteral colic, and renal lesions. Rarely, fulminant hepatic necrosis has been reported.
Other occasional adverse reactions include: urticaria, melaena, haematuria, glycosuria, impaired hearing and tinnitus, abnormal liver function, renal failure and rarely, hepatitis or cholestatic jaundice, flaccid paralysis, and convulsions.

4.9 Overdose
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.
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.

Continuous administration of acetazolamide is associated with metabolic acidosis and resultant loss of diuretic activity. Therefore, the effectiveness of MOXAID Tablets in diuresis diminishes with continuous use.

By inhibiting carbonic anhydrase in the eye, acetazolamide decreases intraocular pressure and is therefore useful in the treatment of glaucoma.

5.2 Pharmacokinetic properties
Acetazolamide is fairly rapidly absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 2 hours after administration by mouth. It has been estimated to have a plasma half-life of about 4 hours. 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. It is excreted unchanged in the urine; renal clearance being enhanced in alkaline urine.

5.3 Preclinical safety data
Not applicable

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Dicalcium phosphate
Corn starch
Magnesium stearate
Sodium starch glycolate
Povidone

6.2 Incompatibilities
None

6.3 Shelf life
48 months

6.4 Special precautions for storage
Do not store above 25°C. Store in the original pack in order to protect from light and moisture

6.5 Nature and contents of container
Polypropylene bottles with polypropylene child resistant screw caps.
Pack size: 112 tablets

6.6 Special precautions for disposal
None.
MARKETING AUTHORISATION HOLDER
Goldshield Pharmaceuticals Limited
NLA Tower
12-16 Addiscombe Road
Croydon
Surrey
CR0 0XT
United Kingdom

MARKETING AUTHORISATION NUMBER(S)
PL 12762/0220

DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
19/10/2011

DATE OF REVISION OF THE TEXT
19/10/2011
Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet as you may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

In this leaflet:
1. What Moxaid 250mg Tablets are and what they are used for
2. Before you take Moxaid 250mg Tablets
3. How to take Moxaid 250mg Tablets
4. Possible side effects
5. How to store Moxaid 250mg Tablets
6. Further information

1. WHAT MOXAIR 250MG TABLETS ARE AND WHAT THEY ARE USED FOR

Moxaid 250mg Tablets contain the active substance Acetazolamide. This belongs to a group of medicines known as carbonic anhydrase inhibitors. Moxaid 250mg Tablets are used to treat:
- Glaucoma due to a build-up of pressure within the eye.
- Cystic fibrosis (Moxaid 250mg Tablets should be used as a dual agent with other therapy).

2. BEFORE YOU TAKE MOXAIR 250MG TABLETS

Do not take Moxaid 250mg Tablets if:
- you have any allergic reaction to carbonic anhydrase inhibitors or any of the other ingredients described under "Ingredients" or to aspirin.
- you have severe liver problems.
- you have or have ever had severe kidney problems.
- you have a particular type of glaucoma known as chronic congestive glaucoma (your doctor will advise you if you have this type of glaucoma). Glaucoma patients should be aware that these tablets may be associated with a change in visual function.
- you have low blood levels of sodium and potassium or high blood levels of chloride (your doctor will advise you).

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

Take special care and speak to your doctor before taking Moxaid 250mg Tablets if:
- you have or have ever had liver or kidney problems.
- you have lung problems such as chronic bronchitis or emphysema, which cause difficulty in breathing.
- you are over the age of 60.
- you are taking or have recently taken any other medicines, including medicines obtained without prescription. The effects of any of these medicines may change, particularly if you are taking, or using, any of the following medicines:
  - 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 other neuroleptic (e.g. phenytoin, primidone or carazolamine or triparanol).
  - drugs which interact with the liver, e.g. rifampicin, ethinylestradiol or fluconazole.
  - drugs used to prevent or treat symptoms of laryngeal oedema or laryngeal oedema due to allergy.
  - anticholinergic medicines (e.g. pseudoephedrine) or other decongestants.
  - diuretics (e.g. hydrochlorothiazide).
  - potassium-sparing diuretics (e.g. amiloride or triamterene).
  - an antidiabetic agent such as glibenclamide.
  - medicines to treat diabetes (e.g. tolbutamide).
  - other medicines called cardiac anhydride inhibitors (e.g. acetazolamide).
  - medicines that are used to treat Alzheimer's disease (e.g. memantine)
  - lithium (lithium carbonate).
  - medicines to lower blood pressure or blood levels of cholesterol.

Tell your doctor if you are or have been pregnant or breastfeeding.

Tell your doctor if you have had or you have a family history of:
- Recurrent fits or epilepsy (i.e. a tendency to have frequent, uncontrolled attacks of fits).
- Injuries to the head, which could affect the brain (e.g. brain tumours or stroke).
- A history of allergic reactions.

3. HOW TO TAKE MOXAIR 250MG TABLETS

Always take the number of tablets your doctor has told you to take. This information will also be on the label.

- Moxaid 250mg Tablets should not be swallowed whole with a drink of water but should be taken with food.
- 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.

USUAL DOSE:
- Glaucoma: Adults: 250mg (1 tablet) every 24 hours, divided dose.
- Cystic fibrosis: Adults: 250mg to 500mg (1 to 2 tablets) every 12 hours, divided dose.
Each tablet contains Acetazolamide 250mg. See leaflet for further information.

For oral administration.

Dosage: Use as directed by the physician. Keep out of the reach and sight of children. Do not store above 25°C.

Store in the original container in order to protect from light and moisture.

PL 12762/0220

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Marketing Authorisation Holder:
Goldshield Pharmaceuticals Ltd, NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey, CR0 0XT, UK.

Lot No:

Use Before:

Each tablet contains Acetazolamide 250mg. See leaflet for further information.

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