

Shortage of Acetazolamide 250mg Prolonged-release Capsules (Advanz/Teva)

Date: 17th April 2020

Description of product affected

- Acetazolamide is a carbonic anhydrase inhibitor. In the eye, it decreases the secretion of aqueous humour and results in a drop of intraocular pressure.
- Acetazolamide SR is a sustained release formulation designed to obtain a smooth and continuous clinical response.
- This formulation is licensed for the treatment of glaucoma and is administered at a dose of 250 to 500mg daily.¹
- There is a branded version manufactured by Advanz of Acetazolamide 250mg prolonged-release capsules, Diamox® (distributed via Alliance Healthcare)
- In Cambridgeshire and Peterborough, acetazolamide formulations are 'Formulary – Specialist Advice, secondary care advice provided for primary care initiation by clinicians.

Where prescribing of acetazolamide is not for the indication of glaucoma, urgent advice and guidance on potential management options should be discussed with the patient's specialist.

Background

Current availability:

- Teva (Eytazox/Generic) - The prolonged release capsules will be out of stock from mid-April until at least July 2020.
- Advanz (Diamox®) – The prolonged release capsules will be out of stock from mid-April until at least July 2020.

Alternative agents and management options

- In the first instance, we would recommend that several local pharmacies and dispensaries are contacted by telephone to ascertain if the patient can be maintained on their usual treatment of acetazolamide SR capsules.
- Acetazolamide immediate release 250mg tablets from several suppliers are available to bridge the gap. The licensed dose for glaucoma is 250 to 1,000mg (1-4 tablets) per 24 hours, usually in divided doses² (plasma half-life of acetazolamide ~ 4 hours³). The tablets vary between manufacturers in whether they have a half or quarter break line.

- Advanz has advised that for glaucoma, patients on 250mg SR capsules twice daily could possibly be switched to 250mg tablets four times daily. This conversion is based simply on the maximum licensed dose of each formulation and would be at the discretion of the prescriber, as there are no bioequivalence studies comparing the two formulations.⁴
- The following data provided by the manufacturer from a single dose study of tablet and sustained release capsule may be helpful when making a dosing decision:⁴

Formulation	Onset (hours)	Peak (hours)	Duration (hours)
Immediate release Tablet	1	1-4	8-12
Sustained release capsule	2	3-6	18-24

Patients should be monitored after the switch as it has been suggested that the prolonged release capsules may be better tolerated than the equivalent dose of immediate release tablets, possibly due to the avoidance of high peak levels.⁵

Alternatively, where the above is not clinically acceptable, unlicensed imports of acetazolamide SR 250mg capsules and an unlicensed oral suspension in various strengths (50mg/5ml, 125mg/5ml, 250mg/ml) are available. If the liquid is used, dosing will be as for the immediate release tablets, with the aforementioned caveats.

For pharmacies:

- Support by checking your current stock levels of these products and informing your local practices of these levels to support local management of patients.
- The patient should be encouraged to try several pharmacies in order to fulfil the prescription as different pharmacies use a range of wholesalers and distributors. The patient may wish to ring pharmacies in advance of attending to ascertain availability.

References

1. ADVANZ Pharma. Diamox SR 250mg Prolonged-release Capsules, SPC, date of revision of the text, 14/08/2019:
<https://www.medicines.org.uk/emc/product/5669/smpc>
2. Crescent Pharma Limited. Acetazolamide Tablets 250 mg, SPC, date of revision of the text, 03/01/2018, accessed via MHRA, 28/03/20:
<https://mhraproductsprod.blob.core.windows.net/docs-20200323/7d420755e964ae5bbcab3e4a619b845af14c6376>
3. ADVANZ Pharma. Acetazolamide 250mg Tablets. SPC, date of revision of the text, 14/08/2019 <https://www.medicines.org.uk/emc/product/2785/smpc>
4. Personal communication, Concordia International Medical Information, 02 April 2020
5. MIDatabank sharer: East Anglian Medicines Information Centre. Acetazolamide - conversion from modified release to immediate release? Enquiry number: 53778

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