

Shortage of Clonidine **25microgram tablets**

Date: 24th December 2019

Description of product affected

- Clonidine, an alpha₂ adrenergic agonist, diminishes the responsiveness of peripheral vessels to constrictor and dilator stimuli, thereby preventing the vascular changes associated with migraine, and moderating the vascular changes associated with menopausal flushing.
- The 25microgram strength of clonidine tablets are licensed for the prophylactic management of migraine or recurrent vascular headache, and the management of vasomotor conditions commonly associated with the menopause and characterised by flushing (initial dose 2 tablets twice daily, increased to 3 tablets twice daily, if no remission after two weeks).¹
- The 25microgram tablets are also used off label in children in Cambridgeshire and Peterborough following specialist advice for the treatment of:
 - Attention deficit hyperactivity disorder with or without oppositionality, or with tic disorder, tourettes syndrome (initial dose 25microgram at night for 1-2 weeks, increase to 50microgram at night. If required dose can be further increased by 25microgram every 2 weeks, side effects permitting. Maximum dose 5microgram/kg/day or up to a maximum of 300microgram/day).²
 - Dystonia (initially, 3microgram/kg three times daily; doses may be escalated rapidly).²

Background

A supplier of clonidine 25microgram tablets is currently out of stock due to manufacturing issues, and is unable to advise on a resupply date, resulting in limited supplies until mid-January 2020.

Alternative agents and management options

The use of low dose clonidine for migraine prophylaxis has been superseded by other agents, such as topiramate or propranolol.³

NICE guidance on the menopause advises against routine use of clonidine as first-line treatment for vasomotor symptoms alone and recommends use of HRT. In women with contraindications to HRT, specialist advice should be sought on other management options.⁴

Where use of clonidine is deemed essential:

- The patient and/or their carer(s) should be encouraged to try several different 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.

- Clonidine also comes as a **50microgram/5ml oral solution**, which has the same licensed indications as the 25microgram tablet (excipients include preservative, methyl parahydroxybenzoate [E218] and sweetening agent, sucralose [E955]⁵; please consult with our Medicines Optimisation Team via CAPCCG.prescribingpartnership@nhs.net or the local paediatric team if there are concerns about these agents in children).
- **Unlicensed imports** of the 25microgram tablets can be sourced from specialist importer companies. However, lead times to order unlicensed imports may vary. Target Healthcare Ltd and Mawdsley's have confirmed they can source unlicensed supplies of clonidine 25microgram tablets. Please note there may be other companies that can also source supplies. Please note:
 - Any decision to prescribe an unlicensed medicine must consider the relevant guidance and local governance procedures.
 - When prescribing a product that is not licensed in the UK, prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done by annotating the prescription with the following wording: "special order".
- If neither of above options are suitable/available, clonidine is available as a **100microgram tablet**, which is licensed for the treatment of hypertension.⁶ The tablets are unscored and splitting them to deliver a smaller dose would be unlicensed. Some centres crush and disperse the tablets in water^{2,7} to deliver a part dose. Please note, this is unlicensed practice. If this option is deemed appropriate, prescribers and pharmacists should ensure that patients and carers are counselled appropriately on how to prepare and administer the dose required accurately.
- An **extemporaneous** preparation of clonidine suspension can also be made if none of the above options are available or are not considered suitable.⁷

References

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3. NICE. Headaches in over 12s: diagnosis and management. Clinical guideline [CG150]. Published September 2012: <https://www.nice.org.uk/guidance/cg150/chapter/Recommendations#management-2>
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5. Thame Laboratories. Clonidine Hydrochloride 50mcg/5ml Oral Solution. SPC, date of revision of the text, 10/08/2018: <https://www.medicines.org.uk/emc/product/9616/smpc>
6. Boehringer Ingelheim Limited. Catapres Tablets 100mcg. SPC, date of revision of the text, June 2018: <https://www.medicines.org.uk/emc/product/2200/smpc>
7. Handbook of Drug Administration via Enteral Feeding Tubes. Clonidine hydrochloride. Accessed via medicinescomplete, 10 Dec 2019

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