Chief Medical Officer Directorate Pharmacy and Medicines Division



18 May 2020

Medicine Supply Alert Notice

Cycloserine 250mg capsules

Priority: Level 2^{*} update to MSAN (2020)20 Valid until: TBC

Issue

- 1. Cycloserine 250mg capsules continue to remain out of stock; this is expected to be a long-term supply issue. There is currently no confirmed resupply date.
- 2. No other licensed strengths of cycloserine are currently marketed in the UK.
- 3. Unlicensed imports of cycloserine 250mg capsules are available.
- 4. The British Thoracic Society has updated its clinical recommendations (see additional information below) regarding the use of alternative agents.

Advice and Actions

- 5. For patients with insufficient supplies to complete their treatment course or for newly initiated patients, clinicians should consider prescribing an unlicensed import of cycloserine 250mg capsules (see additional information below).
- 6. Where unlicensed imports of cycloserine are not considered appropriate, please consider the updated advice from the British Thoracic Society below.

Additional Information

7. Updated clinical recommendations (British Thoracic Society expert advice):

- Cycloserine is indicated for treatment of multi-drug resistant tuberculosis (MDR TB) and is included as one of the first line drugs in the World Health Organisation (WHO) regimen within group B. Therefore, all patients should be offered cycloserine as part of the treatment regimen when a new diagnosis of MDR TB is made.
- The only other alternative to cycloserine is terizidone (group B) which is a derivative of cycloserine.
- Terizidone 250mg capsules are not currently licensed in the UK, however specialist importers have currently confirmed they can source unlicensed terizidone.
- A group C drug (as per WHO regimen) can be added in place of cycloserine, however, this may not be as efficacious.
- Therefore, the recommendation is that unlicensed supplies of cycloserine should be used as the initial alternative option, followed by unlicensed supplies of terizidone before opting for another agent.
- To aid with prescribing, The British Thoracic Society have prepared a clinical monograph for terizidone. Please refer to <u>http://www.tbdrugmonographs.co.uk/uploads/2/8/9/4/28941471/mdrtb_adr_monitoring_guidance_apr_il_2020.pdf</u>
- 8. The following specialist importers have currently confirmed they can source unlicensed cycloserine capsules (please note, there may be other companies that can also source supplies):
 - Alium Medical
 - Clinigen
 - Mawdsleys

*https://nhsnss.org/media/3874/medicine-supply-alert-notices-definitions-of-classifications-21-october-2019.docx

- Target Healthcare Ltd
- WEP Clinical
- 9. The following specialist importer has currently confirmed they can source unlicensed terizidone capsules (please note, there may be other companies that can also source supplies):
 - Clinigen
- 10. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Board local governance procedures. Please see the links below for further information:
 - <u>Prescribing unlicensed medicines</u>, General Medical Council (GMC);
 - <u>The supply of unlicensed medicinal products</u>, Medicines and Healthcare products Regulatory Agency (MHRA); and
 - <u>Professional guidance for the procurement and supply of specials</u>, Royal Pharmaceutical Society (RPS).

Enquiries

11. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to <u>PharmacyTeam@gov.scot</u> (primary care) or <u>NSS.NHSSMedicineShortages@nhs.net</u> (secondary care).