Chief Medical Officer Directorate Pharmacy and Medicines Division



8 April 2025

Medicine Supply Alert Notice

Megestrol (Megace®) 160mg tablets

Priority: Level 2^{*} Valid until: late April 2025

Issue

- 1. Megestrol (Megace®) 160mg tablets are out of stock until late April 2025.
- 2. Medroxyprogesterone (Provera[®]) 200mg and 400mg tablets remain available and can support an increase in demand.
- 3. Medroxyprogesterone (Provera[®]) 100mg tablets remain available but cannot support a full increase in demand.
- 4. Please note that Provera[®] tablets will be available generically as medroxyprogesterone tablets in April 2025.
- 5. Unlicensed supplies of megestrol tablets may be sourced, lead times vary.

Advice and Actions

- 6. Where patients have insufficient supply to last until the re-supply date, prescribers should consider prescribing medroxyprogesterone (Provera[®]) tablets, noting that 200mg and 400mg strengths are able to support the market during this time, ensuring that the patient is not intolerant to any of the excipients and is counselled on the appropriate dose required (see additional information section below).
- 7. Primary care prescribers should seek advice from the specialist team on appropriateness of switching to medroxyprogesterone and dosing, and if this is not considered suitable, on alternative management options.

Additional Information

Clinical Information

- 8. Megestrol (Megace[®]) is a potent progestogen. The tablets are licensed for the treatment of certain hormone dependent neoplasms, such as breast cancer.
- Medroxyprogesterone (Provera[®]) is an alternative progestogen licensed for the treatment of certain hormone dependant neoplasms, such as endometrial cancer, renal cell cancer, and cancer of breast in postmenopausal women. Licensed dosing is 200 to 600 mg daily for endometrial and renal cell cancer and 400 to1500 mg daily for breast cancer.

10. Megestrol and medroxyprogesterone may also be used off label for the treatment of anorexia and cachexia in cancer. Dosing of medroxyprogesterone ranges from 400mg in morning initially, increased as necessary to 400mg to 500mg twice a day.

Links to further information

- SmPC Megestrol (Megace®) 160mg tablets
- <u>SmPC Medroxyprogesterone (Provera®) tablets</u>
- BNF Megestrol
- BNF Medroxyprogesterone

Guidance on ordering and prescribing unlicensed imports

- 11. The following specialist importers have confirmed they can source unlicensed megestrol 160mg tablets (please note there may be other companies that can also source supplies):
 - Clinigen can source a brand called Megefren®
 - Mawdsleys can source a brand called Borea®
- 12. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Health Board or local governance procedures. Unlicensed imports do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes. Please see the links below for further information:
 - <u>The supply of unlicensed medicinal products</u>, Medicines and Healthcare products Regulatory Agency (MHRA)
 - <u>Professional Guidance for the Procurement and Supply of Specials</u>, Royal Pharmaceutical Society
 - <u>Prescribing unlicensed medicines</u>, General Medical Council (GMC)

Specialist Pharmacy Service (SPS) website

- 13. The UK Department of Health and Social Care (DHSC) in conjunction with SPS have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues. To access the online Medicines Supply Tool you need to register with the <u>SPS website</u>. Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.
- 14. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool to stay up to date concerning medicines supply disruptions. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

Enquiries

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