Chief Medical Officer Directorate Pharmacy and Medicines Division



9 November 2020

Medicine Supply Alert Notice

Nalcrom[®] (sodium cromoglicate) 100mg capsules

Priority: Level 2^{*} Valid until: late November 2020

Issue

- 1. Nalcrom[®] 100mg capsules will be out of stock until late November 2020.
- 2. Unlicensed imports of sodium cromoglicate 100mg capsules have been sourced.
- 3. UKMi have sought clinical advice on switching to alternative products.

Advice and Actions

- 4. Where patients have insufficient supplies until the resupply date, clinicians should:
 - prescribe unlicensed imports of sodium cromoglicate 100mg capsules. Prescribers should work with pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see supporting information below); or
 - refer patients to specialists for consideration of an alternative product, taking into account local prescribing guidelines, age and condition being treated if unlicensed imports are not appropriate (see supporting information below).

Additional Information

Guidance on ordering and prescribing unlicensed imports

- 5. The following specialist importers have confirmed they can source unlicensed sodium cromoglicate 100mg capsules (please note there may be other companies that can also source supplies):
 - Alium Medical
 - Mawdsleys Unlicensed
 - Target Healthcare
- 6. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Board or local governance procedures. Please see the links below for further information:
 - Prescribing unlicensed medicines, General Medical Council (GMC),
 - <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

Clinical Information

- 7. Please refer to the BNF/BNFc and SPCs for further information:
 - <u>Nalcrom[®] (sodium cromoglicate) 100mg capsules.</u>
 - Sodium cromoglicate 100mg capsules BNF.
 - Sodium cromoglicate 100mg capsules BNFc.

8. Further resources:

- BNFc section on Food Allergy.
- British Association of Dermatologists leaflet on Urticaria Pigmentosa (cutaneous Mastocytosis).
- NICE evidence searches of Mastocytosis.
- Orphanet evidence summary of systemic Mastocytosis.
- 9. Specialists have advised that where there are insufficient supplies of Nalcrom[®] 100mg capsules, each patient will need to be individually assessed for consideration of an alternative agent(s), taking into account the condition (e.g. food allergy, cutaneous mastocytosis) being treated and previous treatments tried. Potential options include:
 - Zaditen (ketotifen) 1mg tablets.
 - Non-sedating H1 antihistamines.
 - H2 receptor antagonists. (Please note, this is currently being managed as a supply disruption, further information can be found in MSAN(2020)108.

Enquiries

10. 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).