



30 June 2020

Medicine Supply Alert Notice

Fluticasone propionate (Flixotide®) 0.5mg/2ml and 2mg/2ml Nebules

Priority: Level 2*

Valid until: 4 November 2020

Issue

1. Flixotide® 0.5mg/2ml and 2mg/2ml nebulers are out of stock from late June and August 2020, respectively.
2. Re-supplies of both strengths are expected from 4th November 2020.
3. Unlicensed imports of fluticasone 0.5mg/2ml and 2mg/2ml nebulers have been sourced.
4. UKMi have provided clinical advice on switching to alternative inhaled or nebulised corticosteroids.

Advice and Actions

5. Clinicians should identify patients receiving nebulised fluticasone and consider:
 - reviewing the ongoing need for nebulised steroids and consider switching the patient to a steroid containing metered dose inhaler and spacer combination;
 - if the nebulised route is deemed necessary consider prescribing unlicensed imports of fluticasone nebulers (see additional information below); or
 - prescribe alternative steroid nebulers (see additional information below).

Additional Information

Guidance on ordering and prescribing unlicensed imports

6. The following specialist importers have confirmed they can source unlicensed fluticasone nebulers with variable lead times (please note, there may be other companies that can source supplies):
 - Fluticasone 0.5mg/2ml nebulers:
 - Mawdsleys;
 - Alium;
 - Fluticasone 2mg/2ml nebulers:
 - Mawdsleys;
 - Clinigen.
7. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information:
 - [Prescribing unlicensed medicines](#), General Medical Council (GMC);
 - [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA);
 - [Professional guidance for the procurement and supply of specials](#), Royal Pharmaceutical Society (RPS).

Clinical Information

8. For patients who require continued use of a nebulised corticosteroid and where unlicensed imports are not considered appropriate, clinicians should consider switching patients to budesonide nebuliser suspension, bearing in mind there is a lack of definitive data on dose equivalence of nebulised steroids.

	Fluticasone propionate	Budesonide
Presentation	0.5mg/2ml 2mg/2ml	0.5mg/2ml 1mg/2ml
Adult maintenance dose	0.5 to 2mg BD	0.5 to 1mg BD (≥12 years)
Paediatric maintenance dose	1mg BD (age 4 to 16 years)	0.25 to 0.5mg BD (age 3 months to 12 years)

9. Please refer to the SPCs for further information:

- [Fluticasone propionate nebules \(Flixotide® Nebules\)](#);
- [Budesonide nebules \(Pulmicort® Respules\)](#);
- [Budesonide nebules \(Budesonide nebuliser suspension\)](#).

10. Please refer to prescribing guidelines including BNF-C and paediatric formularies for further information on dosing in children.

11. Patients should be monitored after switching and doses titrated according to symptom control. Patients should be advised to contact a healthcare professional should they experience an increase in shortness of breath or increased use of short acting bronchodilator.

Enquiries

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