Chief Medical Officer Directorate Pharmacy and Medicines Division



29 September 2020

Medicine Supply Alert Notice

Sterculia (Normacol[®]) 62% w/w granules Sterculia & Frangula Bark (Normacol Plus[®]) 62%/8% w/w granules

Priority: Level 2^{*} - update to MSAN (2020)87 Valid until: Early October 2020

Issue

- 1. Normacol[®] and Normacol Plus[®] granules are out of stock until early October 2020.
- 2. Unlicensed imports of Sterculia 62% w/w granules and Sterculia 62% w/w with Frangula Bark 8% w/w can be sourced.
- 3. UKMi have provided clinical advice on switching to alternative preparations.

Advice and Actions

- 4. Where patients have insufficient supplies to last until the re-supply date, clinicians should:
 - review if treatment is still required;
 - consider switching to alternative preparations (see supporting information below); or
 - consider prescribing unlicensed imports, if alternative preparations are not considered appropriate. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see additional information below).

Additional Information

Clinical Advice:

Table 1: Alternatives to Normacol[®] and Normacol Plus[®] granules

Product	Container	Dosage	Alternative oral preparation
Normacol® (sterculia) granules	Sachets or lined box of granules	1 or 2 sachets or 1-2 heaped 5ml spoonfuls, once or twice daily after meals.	lspaghula husk* (one sachet up to twice a day)
Normacol Plus® (sterculia / frangula) granules	Sachets or lined box of granules	1 or 2 sachets or 1-2 heaped 5ml spoonfuls, once or twice daily after meals.	Ispaghula husk* (one sachet up to twice a day) with stimulant, e.g. senna (7.5mg – 15mg) at night or bisacodyl (5mg-20mg) tablets.

*if ispaghula products are not suitable/tolerated, methylcellulose is an alternative bulk-forming laxative

5. Due to the aspartame content, ispaghula products are not suitable for patients with phenylketonuria.

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

- 6. Due to maltitol content, senna syrup is not suitable for patients with hereditary problems of fructose intolerance.
- 7. Please refer to the <u>BNF</u> and SPCs for further information on alternative preparations:
 - <u>Normacol granules</u>
 - Normacol plus granules
 - Ispaghula husk products
 - Senna products
 - Bisacodyl products
 - <u>Methylcellulose tablets</u>

Guidance on ordering and prescribing unlicensed imports

8. The following specialist importers have confirmed they can source unlicensed sterculia granules and sterculia granules/frangula bark granules (please note there may be other companies that can also source supplies):

Importer	Product	Container
Alium Medical	Normacol®	Sachets
	Sterculia granules (Normafibre brand)	Lined box
Durbin PLC	Sterculia granules (Normafibre brand)	Sachet
	Sterculia granules/ Frangula bark (Generic)	Lined box
Target Healthcare	Normacol Plus®	Lined box

- 9. 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

Enquiries

10. 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.scot</u> (secondary care).