

Dear Colleague

MEDICINE SUPPLY ALERT NOTICE

Medicine in short supply: Salofalk® (mesalazine) 500mg and 1g suppositories

Priority: Level 2
Valid until: week commencing 16 December 2019

Issue

1. This Medicine Supply Alert Notice provides information regarding the current supply issues for **Salofalk® (mesalazine) 500mg and 1g suppositories**.
2. Salofalk® 500mg suppositories are out of stock until week commencing 16 December 2019. Salofalk® 1g suppositories will be out of stock from from late November until w/c 16th December 2019.
3. Pentasa® (mesalazine) 1g suppositories remain available during this period.

Actions

4. In the absence of Salofalk® suppositories the most practical short-term management option is to convert patients to Pentasa® suppositories.
5. For patients being treated with the 1g strength, it is a straight forward conversion – the dose regimen is identical for both brands.
6. For patients being treated with the 500mg strength, patients could be receiving doses ranging from 500mg twice daily through to 1 g three times a day. Suggested dose changes are as follows:

1 November 2019

Addressees:

For action
Community Pharmacy Scotland
Scottish Prescribing Advisor
Network
Medicines Shortage Response
Group (Scotland)

General Enquiries to:

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- For patients without sufficient supplies of Salofalk[®] suppositories to last until the resolution date, prescribers may consider switching to Pentasa[®] suppositories.
- The below table can be used to support dose conversion between brands:

Salofalk[®]: Existing regimen	Pentasa[®]: Proposed regimen
1g daily	1g daily
500mg twice daily	1 g daily
500mg three times daily	Either 1 g daily (within licence) or 1g twice daily (off label)
2 x 500mg suppositories twice daily	1g twice daily (off label)
2 x 500mg suppositories three times daily	1g three times daily (off label)

7. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and Health Board 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).

Action

8. Healthcare professionals are asked to note the content and actions outlined in this circular and Annex.

Yours sincerely,



Rose Marie Parr
Chief Pharmaceutical Officer/
Deputy Director Pharmacy & Medicines Division

CLASSIFICATION OF MEDICINE SHORTAGES

LEVEL	DESCRIPTION	POTENTIAL RESPONSES
Level one (low impact)	Supply problem with a short duration (up to one month) where <u>immediately available measures are expected to be sufficient</u> and there is minimal additional management requirement.	<p>Business as usual. Response likely to involve using the same medicine.</p> <ul style="list-style-type: none"> Alternative strength/formulation available to meet demand, potentially from other suppliers.
Level two (medium impact)	Supply problem where <u>alternatives in the same therapeutic class are available but which may require some management</u> such as switching to those alternatives, which may include unlicensed medicines.	<p>Business as usual. Response not likely to require a change in the class of medicine.</p> <ul style="list-style-type: none"> Alternative strength/formulation available but clinical advice is required to help manage the switch. Alternative medicine in the same therapeutic class. Unlicensed alternatives may be used. Issuing a Medicine Supply Alert Notice.
Level three (high impact)	<p>Supply problems where there are <u>limited or no alternatives in the same therapeutic class and which require significant management</u>, potentially including changes in clinical practice or operational direction or that have patient safety implications.</p> <p>Level three shortages also include level two shortages for medicines used in <u>life saving conditions</u> such as anaphylaxis or involving <u>patient groups considered as vulnerable</u>, such as neonates, paediatrics or people with learning disabilities.</p>	<p>Serious shortage situation. Response likely to require a change in the class of medicine.</p> <ul style="list-style-type: none"> Alternative therapeutic class of medicine available. The use of a 'serious shortage protocol'. Additional clinical advice. Exceptional MHRA regulatory measures. Issuing a Medicine Supply Alert Notice.
Level four (critical impact)	Supply problems where there is <u>no viable therapeutic alternative</u> and where responses may also require support from outside the health system and / or which trigger the use of national resilience structures.	<p>Very serious shortage situation. Wider burden on NHS and public sector.</p> <ul style="list-style-type: none"> Non-medicine support provided to patients. National Resilience procedures potentially activated – including links with agencies outside NHS. Additional project management or communications support may be required. Issuing a Medicine Supply Alert Notice.