



16 January 2023

Medicine Supply Alert Notice

Sulfasalazine 250mg in 5ml oral suspension sugar free

Priority: Level 2*

Valid until: until early June 2023

Issue

1. Sulfasalazine 250mg/5ml oral suspension sugar free is out of stock until early June 2023.
2. Sulfasalazine 500mg non-enteric coated tablets remain available.
3. A number of Specials manufacturers are able to produce an unlicensed sulfasalazine 250mg/5ml oral suspension.

Advice and Actions

4. Where patients have insufficient supplies to last until the re-supply date, prescribers should:
 - consider prescribing non-enteric coated sulfasalazine 500mg tablets, which are scored, and so can be split to facilitate administration of whole dose, noting that halving the tablet to deliver 250mg dose or crushing the tablets and dispersing in water to deliver a part dose, would be an unlicensed manipulation (see Additional Information below);
 - review patients taking doses that are not in increments of 250mg to consider a dose adjustment to increments of 250mg, where possible;
 - counsel patients on the benefits of using a pill splitter (which can be purchased from a pharmacy or other retail outlets) to ensure a dose as close to 250mg as possible could be obtained, if the decision is taken to halve the tablet;
 - if above options are not appropriate, consider prescribing unlicensed sulfasalazine 250mg/5ml oral suspension available from Specials manufacturers (see Additional Information below).

Additional Information

Clinical Information

5. Non-enteric coated sulfasalazine 500mg tablets are scored to facilitate administration of the tablet as two halves in patients who may find it difficult to swallow the tablet whole. Halving the tablet to deliver a 250 mg dose would be an unlicensed manipulation. If the patient cannot

swallow the half tablet, it could be crushed and mixed in 15 to 30 mL water or soft foodstuff and swallowed. This is also an unlicensed manipulation.

Information about halving tablets

6. A recently published [systematic review](#) of the concerns regarding tablet splitting concluded that with the exception of sustained-release tablets, which should not be split, and excepting those older people who may struggle to split tablets based on physical limitations, there is little evidence to support tablet-splitting concerns.
7. The halving of tablets to ease administration, to deliver a 250mg dose or the crushing tablets and dispersing in water to deliver a part dose, falls outside of the product licence and therefore prescribers must consider relevant guidance and NHS Health Board or local governance procedures as well as consulting with the patient or their carer.

Guidance on ordering and prescribing unlicensed medicines

8. The following Specials manufacturers have currently confirmed they can manufacture sulfasalazine 250mg/5ml oral suspension (please note, there may be other companies that can also manufacture):
 - IPS Pharma
 - Nova Labs
 - Rokshaw
9. 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:
 - [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
 - [Prescribing unlicensed medicines](#), General Medical Council (GMC)

Links to further information

BNF – Sulfasalazine

- [SmPC - Sulfasalazine](#)
- [SPS – Preparing medicines for administration to adults with swallowing difficulties](#)
- [RPS – Pharmaceutical Issues when Crushing, Opening or Splitting Oral Dosage Forms](#) [BJGP Open – Concerns regarding tablet splitting: a systematic review](#)

Specialist Pharmacy Service (SPS) website

10. 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.

11. To access the online Medicines Supply Tool you need to register with the [SPS website](#). Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Planning tab and then click on the Medicines Supply option.
12. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool in order to stay up to date concerning medicines supply disruptions.
13. 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

14. 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).