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Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
Riaghaltas na h-Alba
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Medicine Supply Alert Notice

Mesalazine (Asacol®) 400mg MR gastro-resistant tablets

Priority: Level 2*
Valid until: discontinued - stock to be exhausted by late April 2024

Issue

1. Asacol® 400mg MR gastro-resistant tablets (pack size 168) was discontinued in March 2024; all stocks have now been exhausted.
2. Asacol® 400mg MR gastro-resistant tablets (pack size 84) was discontinued from 1st April 2024; stocks are expected to be exhausted from late April 2024.
3. Mesalazine (Octasa® MR) 400mg tablets remain available and can support a full uplift in demand.
4. Mesalazine (Asacol®) 800mg MR gastro-resistant tablets remain available and able to support a full uplift in demand.
5. Other mesalazine tablet preparations, with different release characteristics, remain available should above options not be considered suitable.
6. Unlicensed imports of mesalazine (Asacol®) 400mg MR gastro-resistant tablets can be sourced, lead times vary.

Advice and Actions

7. Prescribers should not initiate new patients on Asacol® 400mg modified-release gastro-resistant tablets and review patients currently prescribed this product to:

    - consider prescribing Octasa® 400mg MR tablets, reassuring patients that this is a similar preparation to Asacol® 400mg MR gastro-resistant tablets; or
    - consider prescribing Asacol® 800mg MR gastro-resistant tablets for patients using two Asacol 400mg MR tablets to make up dose of 800mg, if this is deemed the most appropriate brand, and counsel patients on change in number of tablets to be taken; or
    - refer to the SPS Guidance Switching between mesalazine oral tablet preparations for further information on licensed indications and dosing of other brands of mesalazine tablets if the above options are not considered appropriate, taking into account different release characteristics;
    - review and update local policies, guidelines and formularies where they include Asacol 400mg tablets;
    - counsel patients on any new product prescribed;
    - consider prescribing unlicensed products only where licensed alternatives are not appropriate. Prescribers should work with local pharmacy teams to ensure orders are placed

***https://www.nss.nhs.scot/media/1842/medicine-supply-alert-notices-definitions-of-classifications-21-october-2019.pdf**

within appropriate time frames as lead times may vary (see Additional information below); and
- monitor patients for disease control and tolerability of treatment after switching products and ensure they are maintained on this brand if the switch is successful.

Additional Information

8. Asacol® MR tablets are licensed for:

- treatment of mild to moderate acute exacerbations of ulcerative colitis and maintenance of remission
- maintenance of remission in Crohn's ileo-colitis.

9. The tablet coating disintegrates and releases mesalazine when pH is above 7, so this would take place in the terminal ileum and large bowel.
10. Asacol® MR 800mg tablets should not be halved to deliver a 400mg dose as the tablets are coated with an acrylic-based resin to delay release of mesalazine until it reaches the terminal ileum and beyond.

Alternative mesalazine tablet preparations

11. The BNF states there is no evidence to show that any one oral preparation of mesalazine is more effective than another; however, the delivery characteristics of oral mesalazine preparations may vary.
12. Octasa® MR tablets are a branded generic version of Asacol® tablets. They are coated with a pH responsive polymer which enables the release of mesalazine only at a pH above 7, i.e., within the terminal ileum and colon. They have virtually the same in vitro dissolution profile, pH for release, and site of drug release as Asaco®l tablets.

Links to further information

- Mesalazine BNF
- Asacol® SPC
- Octasa® SPC
- SPS Guidance: Switching between mesalazine oral tablet preparations

Guidance on ordering and prescribing unlicensed imports

13. The following specialist importers have confirmed they can source unlicensed Asacol® 400mg MR gastroresistant tablets (please note there may be other companies that can also source supplies):

- Genetech (pack size 60)

14. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Health Board or local governance procedures. Unlicensed imports do not undergo any

central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes.

15. 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).

Specialist Pharmacy Service (SPS) website

16. 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. 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 Tools tab and then click on the Medicines Supply option.
17. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool to stay up to date concerning medicines supply disruptions. 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

18. 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).