Department of Health & Social Care

NHS England

Medicine Supply Notification

MSN/2024/028

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

Tier 2 – medium impact*
Date of issue: 25/04/2024
Link: Medicines Supply Tool

Summary

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

Actions Required

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 within appropriate time frames as lead times may vary (see supporting 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.

*Classification of Tiers can be found at the following link:
https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/

Supporting information

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.

The tablet coating disintegrates and releases mesalazine when pH is above 7, so this would take place in the terminal ileum and large bowel.

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

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.

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 Asacol® 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

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

- Genetech (pack size 60)

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust 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.

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),

When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done in one of the following two ways:

Electronic prescriptions – if the required unlicensed product is shown on electronic prescribing systems, GPs should select:

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

Paper prescriptions – where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: “**special order**”.

Enquiries

If you have any queries, please contact DHSCmedicinesupplyteam@dhsc.gov.uk