

SWITCH FROM ASACOL® OR GENERIC MESALAZINE TO OCTASA® IN PRIMARY CARE

Summary

Octasa® contains modified-release mesalazine and is a clinically equivalent branded generic version of Asacol®. Using Octasa® in place of Asacol® would deliver significant savings to Suffolk and North East Essex as the cost of Asacol® is significantly more than Octasa®.

NHS North East Essex CCG (NEECCG) and NHS Ipswich and East Suffolk CCG (IESCCG) together with the Gastroenterology teams at East Suffolk and North Essex Foundation Trust (ESNEFT) support the switch from Asacol® to Octasa® in appropriate patients.

BACKGROUND

Mesalazine is an aminosalicilate that is used routinely to induce and maintain remission in chronic inflammatory bowel disease such as Ulcerative colitis (UC) or Crohn's Disease⁽¹⁾.

There are a number of different brands of mesalazine available in the UK some of which have different delivery characteristics⁽²⁾ and are therefore not easily interchangeable. The BNF does state that there is **no evidence** that one oral preparation of Mesalazine is more effective than another⁽³⁾.

Octasa® MR 400mg tablets and Asacol® MR tablets 400mg have a virtually identical in vitro dissolution profile, optimal pH for release, site of drug release and similar formulations as they both have Eudragit S enteric coatings(See Table 1)⁽⁴⁾.

The Gastroenterology teams for ESNEFT support the decision for patients to be switched from Asacol MR to Octasa MR in primary care given that no change in response is expected.

ESNEFT start all new patients on Octasa® and are in agreement that existing patients on Asacol® tablets can be switched to Octasa® in primary care, providing they do not meet the exclusion criteria.

HOW TO SWITCH

1. Review all patients currently prescribed (searches have been created for EMIS and SystemOne practices):
 - a. Asacol® MR 400mg tablets
 - b. Asacol® MR 800mg tablets
 - c. Mesalazine MR 400mg tablets (generically written)
 - d. Mesalazine MR 800mg tablets (generically written)

THIS SWITCH DOES NOT APPLY TO ANY OTHER FORMULATION OR STRENGTH OF MESALAZINE

2. Ensure that the patient does not meet one of the following exclusion criteria:

Exclusion criteria:

- Patients who have a documented adverse reaction or reduction in symptom control to Octasa®.
- Patients who have been taking Asacol® for less than 12 months.
- Patients who have had disease activity, i.e. not in remission, in the last 12 months [symptoms consistent with disease activity (i.e. a flare-up that has required steroids) and / or raised faecal calprotectin >200mcg/g]
- Patient is on another brand of Mesalazine other than Asacol®

3. Switch to branded Octasa® MR 400mg or 800mg tablets at the same dose and frequency.
4. A patient letter is available to support this switch.
5. The patient should be advised to report any changes in symptoms to the healthcare professional who undertook the review.

MONITORING

Octasa® has almost identical release characteristics as Asacol®, so patients should not develop deterioration in symptom control.

However, if the patients return to the GP with a reduction in symptom control they should be permitted to return to their previous brand; although this is not something that it is anticipated as being a problem.

If the patient becomes symptomatic please review the ESNEFT, NEECCG and IESCCG *Guidelines for Monitoring Mesalazine for Inflammatory Bowel Disease in primary care* ([please click here](#)) and liaise with the gastroenterologists for advice in line with the guidance.

ASACOL ® AND OCTASA ® COMPARISON TABLE

Drug	Formulation	Optimal drug release pH	Site of drug release	Licensed age restriction
Asacol ® MR	400mg: Enteric coated with Eudragit S	>7	Terminal ileum and large bowel (colon and rectum)	≥ 18 years
	800mg: Enteric coated with Eudragit S and Eudragit L	>6-7		≥ 18 years
Octasa ® MR	Enteric coated with Eudragit S	>7	Terminal ileum and colon	> 6 years

Figure 1: Comparison of formulation and release characteristics of Asacol ® and Octasa ® MR tablets ⁽⁴⁾

REFERENCE

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4. **PrescQIPP Community Interest Company.** *Branded mesalazine modified release (MR) prescribing.* s.l. : PrescQIPP, December 2019. 249.
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