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PAN MERSEY AREA PRESCRIBING COMMITTEE

PRESCRIBING POLICY STATEMENT

REF: PS230 FINAL

APC BOARD DATE: 28 FEB 2018



Pan Mersey

Area Prescribing Committee

## MESALAZINE oral formulations

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The Pan Mersey Area Prescribing Committee recommends the prescribing of Mesalazine oral formulations by brand name following specialist initiation for inflammatory bowel disease.

Octasa<sup>®</sup> brand is considered to be equivalent to Asacol<sup>®</sup> brand and currently represents a more cost effective choice.

### FOLLOWING SPECIALIST INITIATION

**OCTASA<sup>®</sup> modified release (M/R) tablets** are licensed as follows<sup>1</sup>

- for mild acute ulcerative colitis; 2.4g once daily or in divided doses, with concomitant corticosteroid therapy where clinically indicated.
- for moderate acute ulcerative colitis; 2.4g to 4.8g a day with concomitant corticosteroid therapy where clinically indicated. The 2.4g dose may be taken once daily or in divided doses. Doses above 2.4g should be taken in divided doses.
- for the maintenance of remission of ulcerative colitis and Crohn's ileocolitis; 1.2g to 2.4g once daily or in divided doses.

Octasa<sup>®</sup> is released in the terminal ileum and colon

**Note:** Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

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(or earlier if there is significant new evidence relating to this recommendation)

## Mesalazine Oral Formulations

<p><b>EFFECTIVENESS</b></p> <p>Octasa® tablets are coated with a Eudragit S-based film which allows the mesalazine to be released when the intraluminal pH is greater than 7 ie. within the terminal ileum and colon<sup>2</sup>.</p> <p>Octasa® is similar to Asacol® in terms of formulation, optimal pH for drug release and site of drug release and dissolution studies have demonstrated very similar dissolution profiles<sup>2</sup>.</p> <p>For ulcerative colitis, efficacy may depend more on adherence with the prescribed dose than the delivery system<sup>3</sup>.</p> <p>NICE state that the person's preferences, side-effects and cost should be taken into account when deciding which oral aminosalicylate to use<sup>4</sup>.</p>	<p><b>SAFETY<sup>5</sup></b></p> <p><b>Contraindications:</b> salicylate hypersensitivity, severe renal impairment (GFR &lt; 20 ml/min/1.73m<sup>2</sup>), severe hepatic impairment</p> <p><b>Special Warnings and precautions for use:</b> mild to moderate renal impairment, , elderly, pulmonary disease</p> <p><b>Adverse effects.</b> Rare; Acute pancreatitis; agranulocytosis; alopecia; aplastic anaemia; arthralgia; blood disorders; eosinophilia; fibrosing alveolitis; hepatitis; interstitial nephritis; leucopenia; lung disorders; lupus erythematosus-like syndrome; methaemoglobinaemia; myalgia; myocarditis; nephrotic syndrome; neutropenia; pericarditis; peripheral neuropathy; renal dysfunction; skin reactions; Stevens-Johnson syndrome; thrombocytopenia; dizziness</p> <p>See individual SPCs for full details.</p>
<p><b>COST</b> for one year's treatment<sup>7</sup></p> <p>Octasa® 2.4g daily (using 400mg MR tablets) = £402.34</p> <p>Octasa® 2.4g daily (using 800mg MR tablets) = £489.88</p> <p>Asacol® 2.4g daily = £713.70</p> <p>For information, other brands available include;</p> <p>Salofalk® 1g tds (using 250mg tablets) = £707.18</p> <p>Pentasa® SR 2g daily = £447.60</p> <p>Mezavant® 2.4 g daily = £521.13</p>	<p><b>PATIENT FACTORS</b></p> <p>Use in the elderly should be cautious and subject to patients having normal renal function.</p>

### PRESCRIBING INFORMATION

Due to the risk of serious blood dyscrasias, patients should be advised to report any unexplained bleeding, bruising, purpura, sore throat, fever or malaise that occurs during treatment. A full blood count should be performed and mesalazine stopped immediately if there is suspicion of a blood dyscrasia<sup>5</sup>.

Renal function should be monitored before starting treatment, after 3 months and then annually (more frequently in renal impairment)<sup>5</sup>.

### IMPLEMENTATION NOTES

Prescribe mesalazine MR 400mg and 800mg by brand name for all new patients, in line with NICE CG 166<sup>4</sup> and 152<sup>6</sup> and guidance from the British Society of Gastroenterology<sup>3</sup>. Currently Octasa® MR tablets 400mg and 800mg is more cost effective than Asacol<sup>7</sup>. If switching a patient to a different brand of mesalazine, the patient should be advised to report any changes in symptoms.

#### Recommended Switching Procedure

##### Secondary Care

Identify all patients currently prescribed generic M/R mesalazine 400mg or 800mg tablets, or Asacol® brand either proactively or at review.

Prescriber reviews clinical records to establish whether the patient has experienced a previous relapse of their disease after switching to Octasa® or Mesren® in the past. In these cases, ensure that Asacol® is prescribed by brand and the GP is informed of the decision. For all other cases, discuss with the patient and/or carer and switch to Octasa® if appropriate. Document in clinical records and ensure the GP is informed of the decision. Monitor as appropriate.

##### Primary Care

Obtain agreement from the practice.

Identify all patients currently prescribed generic M/R mesalazine 400mg or 800mg tablets, or Asacol® brand.

Review patient records and identify cases where the patient has experienced a previous relapse of their disease after switching to Octasa® or Mesren® brand in the past- these patients will continue on Asacol brand®, ensure the mesalazine is prescribed by brand on the clinical system.

All other cases should be considered for switching to the same dose of Octasa® brand provided that the patient is clinically stable (defined as no documented disease flares within the last 6 months and no hospital admissions for inflammatory bowel disease within the last 6 months) and has no history of intolerance to Octasa® brand (formerly known as Mesren®) . Discuss with the patient and/or carer and switch. Monitor as appropriate.

### REFERENCES

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