SHARED CARE AGREEMENT
MESALAZINE in the treatment of Paediatric Colitis

Sharing of care assumes communication between the specialist, GP and patient, and other members of the team including specialist nurses and pharmacists. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

If a GP is invited by the specialist to participate in a shared care arrangement, the GP should reply to this request within 10 working days. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

This Shared Care Agreement covers patients with Ulcerative Colitis and Mild to Moderate Indeterminate Colitis (which is treated as colitis although shows features similar to Crohn's), only.
It will be offered if PUCAI (Paediatric Ulcerative Colitis Activity Index) score continues to categorise patient as 'in remission', 'mild' or 'moderate'.

Ulcerative colitis is a non transmural condition involving the colon. This may be classified as follows: Proctitis, Left sided disease or Pancolitis. If this does not respond to local therapy it requires oral treatment with mesalazine, with or without an adjunctive corticosteroid.
The disease is lifelong and characterised by episodes of relapse and remission. Relapses are not predictable and patients with frequent relapses will require intervention with corticosteroids.
Patients who need repeated courses of corticosteroids may require immunomodulating agents for maintaining remission and treatment of active disease, either 6-mercaptopurine or azathioprine.

Mesalazine is an aminosalicylate licenced for the treatment of acute attacks of mild to moderate UC and maintenance of remission. Current recommended formulary brands are Octasa® and Pentasa®.
Octasa is licenced in those aged 6 and over, Pentasa® prolonged release granules and tablets are licensed from age 6.

**Specialist responsibilities**

1. Diagnosis of condition and ensuring other treatment options have been fully explored. Patients/carers are provided with the patient information leaflet before commencing therapy.
2. Discuss the benefits and side-effects of treatment with the patient. Ensure that patient/carer is aware of what potential adverse symptoms to report. Record that information has been given and is understood by the patient in the notes.
3. Perform baseline and follow up tests including renal function annually (see Appendix)
4. Prescribe initial course of treatment (3 months) and arrange testing and full monitoring for the first 3 months.
5. Follow up of children including review of blood results. Adjust treatment as appropriate for the individual patient.
6. Monitor for response and adverse drug reactions (ADRs) during initial course.
7. Liaison with the general practitioner (GP) to share the patient's care after the first 3 months using the Shared Care Request Form. Shared care should not be assumed until a written agreement has been received from the GP.
8. Periodically review the patient's condition and communicate promptly with the GP in writing when to adjust the dose, stop or change treatment and when to consult with the specialist.
9. Report adverse events to the MHRA and GP.
10. Respond to issues raised by GP. Advise GP on related issues such as drug interactions etc. Ensure that clear backup arrangements exist for GPs to obtain advice and support.
**GP responsibilities**

1. Confirm or decline request to share patient’s care within 10 working days, using the shared care request form.
2. Prescribe treatment at the dose recommended (and by brand for mesalazine) in accordance with the specialist’s request and the BNF for Children.
3. Check blood results available are in line with frequency specified in the Appendix before issuing a prescription. Seek advice from a Paediatric Gastroenterologist in cases of concern.
4. GPs are not expected to adjust doses or stop treatment unless on the advice of a specialist.
5. Ensure compatibility with other concomitant medication.
6. Adjust the dose or stop treatment on the advice of a specialist. Stop treatment immediately if an urgent need to cease treatment arises.
7. Ensure advice is sought from the secondary care clinician if there is any significant change in the patient’s physical health status.
8. Report adverse events to the specialist and MHRA.

**Community pharmacist responsibilities**

1. Check patient is taking the medicine as prescribed.
2. Check the patient is attending for monitoring as outlined below.
3. Ensure compatibility with other concomitant medication, including over the counter medicines.
4. Report any concerns to the GP.

**Patient/family/parent responsibilities**

1. Do not miss any blood tests or other appointments without first consulting the GP or specialist.
2. Report to the specialist or GP if he/she does not have a clear understanding or has concerns in relation to the treatment.
3. Inform specialist, GP or pharmacist of any other medication being taken, including over the counter products.
4. Report any adverse effects or warning symptoms to the GP or specialist.
5. Inform other professionals of current treatments as necessary.

**Further advice and support - this information is not inclusive of all prescribing information**

Consultant Paediatric Gastroenterologists (Dr A Willmott, Dr H Bhavsar, Dr S Pande)
Leicester Royal Infirmary (0116) 258 6794 or on-call consultant via UHL switchboard 0300 3031573
Vicky Worthy, Paediatric Clinical Pharmacist, UHL.


Summary of product characteristics via [electronic Medicines Compendium (eMC)](https://www.medicinescomplete.com/mc/bnfc/current/)


Trent Regional Medicines Information Centre, Victoria Building, Leicester Royal Infirmary, LE1 5WW
Tel: 0116 258 6491 Fax: 0116 258 5680. Email for enquiries: medicines.info@uhl-tr.nhs.uk
### Appendix

<table>
<thead>
<tr>
<th>Drug</th>
<th>Pre-treatment</th>
<th>Routine</th>
<th>Discuss with specialist urgently</th>
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<tbody>
<tr>
<td>Mesalazine</td>
<td>U&amp;Es, creatinine</td>
<td>U&amp;Es and creatinine at 3 months after starting then annually (for patients with renal impairment seek specialist advice).</td>
<td>Suspected renal dysfunction</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Unexplained bleeding, purpura anaemia persistent fever or sore throat, (possible blood dyscrasia)</td>
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<td>Suspected liver dysfunction</td>
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**Prescribe by brand, see Leicestershire Formulary**