Drug Monitoring for Sulfasalazine and Mesalazine (Aminosalicylates) in Inflammatory Bowel Disease in Primary Care

This monitoring guidance is an aid for prescribing and in no way obligates the GP to prescribe these drugs. As always GPs should prescribe only when they feel confident to do so.

Please refer to the SPC (www.emc.medicines.org.uk) or current BNF for further prescribing information. http://www.bnf.org/bnf/index.htm

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<th>Safety Monitoring Parameter</th>
<th>Action required if abnormal results</th>
<th>Additional Notes</th>
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<td><strong>Sulfasalazine (Sulphasalazine)</strong></td>
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<td>Baseline</td>
<td>At Initiation</td>
<td>Maintenance</td>
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<td>FBC, LFTs, U&amp;Es</td>
<td>Check FBC and LFT’s every fortnight for one month and then monthly for 2 months. U&amp;E’s should be checked after 3 months therapy. NB: Urgent FBC is required if patient complains of intercurrent illness during initiation of therapy</td>
<td>If dose and blood results stable, FBC, LFTs and U&amp;E’s should be monitored every 3 months. More frequent blood tests are required in the following circumstances: • after a dosage increase or a continuing downward trend in WBC or neutrophil count In these situations, FBC and LFT’s should be monitored every 2 weeks for one month. NB: Urgent FBC is required if patient complains of intercurrent illness.</td>
<td>Stop drug and liaise with Gastroenterologist if: WBC &lt; 4.0 x 10⁹/l or Neutrophil &lt; 2.0 x 10⁹/l or Platelets &lt; 150 x 10⁹/l or &gt;2 fold rise in AST or ALT (from upper limit of reference range) Or Oral ulceration Please note that in addition to absolute values of haematological indices a rapid fall or consistent downward trend in any value should prompt caution &amp; extra vigilance. Patient should be asked about the presence of rash or oral ulceration at each visit. Patients to report immediately any unexplained bleeding, bruising, purpura, sore throat, fever, malaise or unexpected non-specific illness. In the presence of a unexplained acute widespread rash – withhold drug and seek urgent specialist advice. Abnormal bruising or severe sore throat – Check FBC immediately and withhold until results available. Discuss with specialist if necessary. Stop drug if suspect signs of myelosuppression, haemolysis or hepatotoxicity and liaise with Gastroenterologist.</td>
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<tr>
<td>Mesalazine</td>
<td>Renal Function Monitoring</td>
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<td>The BNF (issue 65) recommends that renal function should be monitored before starting an oral aminosalicylate, at 3 months of treatment,</td>
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<td>BNF 65</td>
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and then annually during treatment (more frequently in renal impairment).

The SPC (Asacol® brand) recommends the following:

“Patients on mesalazine should have renal function monitored, (with serum creatinine levels measured) prior to treatment start. Renal function should then be monitored periodically during treatment, for example every 3 months for the first year, then 6 monthly for the next 4 years and annually thereafter, based on individual patient history. Physicians should take into account risk factors such as prior and concomitant medications, duration and severity of disease and concurrent illnesses. Treatment with mesalazine should be discontinued if renal function deteriorates. If dehydration develops, normal electrolyte and fluid balance should be restored as soon as possible.

Blood Disorders

The BNF (issue 65) recommends that patients receiving Aminosalicylates should be advised to report any unexplained bleeding, bruising, purpura, sore throat, fever or malaise that occurs during treatment. A blood count should be performed and the drug stopped immediately if there is suspicion of a blood dyscrasia.

PRIMARY CARE PRESCRIBING RESPONSIBILITIES

Assessment and Monitoring
- Receive copies of any blood test results carried out in secondary care.
- Send copies of any blood test results carried out in primary care to the Specialist.
- Monitor the patient for any side-effects to therapy and refer back to the Specialist should any serious side-effect occur.
- Refer back to the Specialist if the medication becomes less effective.

Prescribing Arrangements
- Take over prescribing of drug when clinically appropriate – after about 1-3 months of therapy (but this may vary depending on drug used and time to stabilisation).
- **As the prescribing clinician, ensure that the relevant blood test monitoring is carried out and the results are checked.**
- Provide repeat prescriptions and adjust dosages on the advice of the Specialist.
- Advise Specialist of any other dosage adjustments made, with reasons.

Communication
- To ensure that all relevant staff and patients are aware of the shared care arrangements.
- Blood test results, dosage adjustments, will be recorded in the hospital and GP medical records (including computer-based prescribing systems).
- The dosage regimen should be clearly explained to the patient.
- The patient should be asked to report side-effects.

References:

1. Toolkit to support development of medicines management arrangements with secondary and tertiary care services, Medicines Management, Pharmacy and Prescribing SIG High Priority Competencies, NaTPACT, March 2004.
7. Sulfasalazine for the Treatment of rheumatoid arthritis, Luton Specific Brief Shared Care guideline, Dec 2013, available on GP Ref Website.