

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>

Sulfasalazine (Sulphasalazine)

Safety Monitoring Parameter ^{1,2,3,4}			Action required if abnormal results
Pre-treatment	Monitoring until stable	Ongoing monitoring	
FBC, LFTs, U&Es	<ul style="list-style-type: none"> FBC, U+E, LFT fortnightly until dose and monitoring stable for 6 weeks, then monthly for 3 months then every 12 weeks* thereafter. <p>*More frequent monitoring is appropriate for patients at a higher risk of toxicity.</p>	<ul style="list-style-type: none"> After 12 months, the patient should be reviewed. If patient is on a stable dose and blood tests results have been within normal limits, after 12 months, routine blood test monitoring can be discontinued. More frequent blood tests are required in the following circumstances: <ul style="list-style-type: none"> After a dosage increase In these situations, FBC and LFT's should be monitored every 2 weeks for 6 weeks. NB: Urgent FBC is required if patient complains of intercurrent illness. 	<p>Stop drug and liaise with Gastroenterologist if:</p> <p>WBC < 4.0 x 10⁹/l or Neutrophil < 2.0 x 10⁹/l or Platelets < 150 X 10⁹/l or >2 fold rise in AST or ALT (<i>from upper limit of reference range</i>) Or Oral ulceration</p> <p>Please note that in addition to absolute values of haematological indices a rapid fall or consistent downward trend in any value should prompt caution & extra vigilance.</p>

Mesalazine

Monitoring advice based upon consensus opinion ^{4,5,6,7}		Action required if abnormal results
Pre-treatment tests	FBC, U&E, LFTs	Mesalazine should be discontinued if renal function deteriorates. AST, ALT > twice upper limit of reference range, withhold treatment until discussed with the specialist team.
Monitoring until stable	FBC, U&Es, LFTs and renal function every 3 months for the 1st year.	
Ongoing monitoring	FBC, U&Es, LFTs annually or more frequently if required based on individual risk factors	

Additional notes

Patients taking aminosalicylates should be counselled to report any unexplained bleeding, bruising, sore throat, fever, or malaise. Perform a full blood count and stop treatment immediately if a blood dyscrasia or toxicity is suspected. Ask about the presence of rash or oral ulceration at each visit.

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. SPC for Salazopyrin En® tablets (2010) <https://www.medicines.org.uk/emc/product/6686/smpc>
2. Bedfordshire Joint Prescribing Committee Rheumatology Shared Care Guidelines for DMARDs, available on GP Ref
3. Bedfordshire Joint Prescribing Committee DMARDs in Adult Rheumatology – Sulfasalazine, available on GP Ref
4. BSG Guidelines for the management of inflammatory bowel disease in adults, Lamb, Kennedy, Raine *et al* Gut (2019)
5. SPC for Asacol 400mg MR tablets (2015) <https://www.medicines.org.uk/emc/product/2217>
6. SPC for Octasa 400mg MR tablets (2017) <https://www.medicines.org.uk/emc/product/2827/smpc>
7. Suggestions for Drug Monitoring for Adults in Primary Care, NHS UKMI (2017) https://www.sps.nhs.uk/wp-content/uploads/2017/12/Drug-monitoring_October-2017.pdf
Dec 2008 (Original document), updated Sept 2013, Dec 2013 & September 2019