

Guidelines for Monitoring Mesalazines for Inflammatory Bowel Disease in primary care

This guideline outlines the cautions and contraindications monitoring requirements, specialist responsibilities, and transfer of prescribing responsibilities and follow-up to GP care.



<p>Patient ID Label</p> <p>Surname: _____</p> <p>Forename: _____</p> <p>NHS Number: _____</p> <p>Date of Birth: _____</p>	<p>Consultant Gastroenterologist contact details</p> <p>Name: _____</p> <p>Hospital: _____</p> <p>Tel: _____</p> <p>Date: _____</p>
--	--

Indications	Mesalazine is the standard therapy for mild to moderate active ulcerative colitis (UC). It is also licensed in the maintenance of remission of Crohn's ileo-colitis. Mesalazines should ALWAYS be prescribed by brand name. In an evaluation of data from Cochrane analyses there were no differences between the various mesalazine formulations in terms of efficacy. The best drug should therefore be selected taking into account patient preference for formulation, tablet size and number required daily, in order to maximise treatment adherence while considering cost.
Contraindications	<ul style="list-style-type: none"> • A history of sensitivity to salicylates or where there is renal sensitivity to sulfasalazine. • Severe renal impairment (CKD stages 4 and 5 with a GFR (Cockcroft-Gault) less than 20ml/minute).
Cautions	<p>Discontinue mesalazine if renal function deteriorates.</p> <ul style="list-style-type: none"> • Use with caution in the elderly (>70 years old) and only when renal function is normal. • Use of mesalazine during pregnancy should be with caution, and only if the potential benefits are greater than the possible hazards. Unless essential, it should be avoided by nursing mothers.
Monitoring	<p>See table overleaf</p> <ul style="list-style-type: none"> - Baseline bloods to be requested and checked by clinician providing the first prescription. - Ongoing monitoring by GP practice.
Specialist responsibilities	If specialist providing the first prescription - ensure baseline bloods ((U&Es) FBC, LFT'S) are within recommended range.
GP responsibilities	<p>Key roles to be undertaken in primary care following a recommendation from secondary care:</p> <ul style="list-style-type: none"> • Check baseline bloods are within recommended range. • Monitor biochemistry periodically as per recommendations overleaf or as indicated by the specialist. The aim of the treatment is to manage symptoms of UC whilst ensuring (U&Es) FBC, LFT's remain stable. • Report to and seek advice from the specialist on any aspect of patient care, which is of concern and may affect treatment. • Report adverse events to the MHRA on a Yellow Card www.mhra.gov.uk/yellowcard and to the specialist.

The manufacturer's summary of product characteristics (SPC) and the most current online edition of the British National Formulary should be consulted for full information on contraindications, warnings, side effects and drug interactions.

References

1. British National Formulary. Accessed online via: <http://www.medicinescomplete.com> on 2/7/2020
2. Summary of Product Characteristics for Octasa® 800mg MR Tablets (mesalazine). Last updated on the eMC 20 NOV 2020. Accessed online via: <http://www.medicines.org.uk/emc/> on 31/7/2020
3. NICE CKS last revised April 2020. Ulcerative colitis. Accessed online via: <http://cks.nice.org.uk/> on 31/7/2020
4. BSG Consensus Guidelines for the management of IBD in adults – 2019
5. The Renal Drug handbook <https://renaldrugdatabase.com/monographs/mesalazine>, accessed 11/8/2020

MONITORING

	Parameter	Frequency		
	In addition to absolute values for haematological indices, a rapid fall or rise and a consistent upward or downward trend in any value should prompt caution and extra vigilance			
Specialist	Urea & Electrolytes (U&Es) including creatinine	<ul style="list-style-type: none"> • Prior to starting treatment. • Annually as part of inflammatory Bowel Disease monitoring. 		
	FBC			
	LFTs			
	Parameter	Frequency	Action for GP to take if abnormal result	
GP	U&Es including creatinine	3 monthly for the first year; then 6monthly for the next 4 years ; then annually thereafter. Those with impaired renal function should be monitored more closely taking into consideration patient factors such as age, other medicines etc.	Discontinue treatment if the patient's renal function deteriorates GFR <50ml/min (Cockcroft - Gault)	
	Full Blood Count (FBC)	<ul style="list-style-type: none"> • If haematological adverse effects are suspected 	<ul style="list-style-type: none"> • White blood count (WBC) <4x10⁹/l 	Check neutrophil count
			<ul style="list-style-type: none"> • Neutrophils <2.0x10⁹/l 	Monitor weekly. If falls below 1.5x10 ⁹ /l STOP DRUG and contact the IBD team.
			<ul style="list-style-type: none"> • Platelets <150x10⁹/l 	Monitor weekly. If drop below 100x10 ⁹ /l contact IBD team. IBD team to monitor /restabilise the patient before transferring care back to primary care.
<ul style="list-style-type: none"> • Mean corpuscular volume (MCV)>105 fl 			Check serum B12 and folate and if low start appropriate supplements depending on blood levels as per BNF.	
Liver Function Tests (LFTs)	<ul style="list-style-type: none"> • If hepatic adverse effects are suspected 	<ul style="list-style-type: none"> • Aspartate transaminase (AST), alanine aminotransferase (ALT) > three times upper limit 	Monitor weekly. If ALT continues to rise, contact IBD team if any clinical concerns. IBD team to monitor /restabilise the patient before transferring care back to primary care.	
Symptoms		Action for GP to take if symptom occurs		
GP	Rash	<ul style="list-style-type: none"> • STOP DRUG and contact IBD team for further advise 		
	Severe oral ulceration	<ul style="list-style-type: none"> • STOP DRUG, Corlan pellets (hydrocortisone buccal tablets – one tablet allowed to dissolve slowly against the mouth ulcer(s) – Four times a day) and contact IBD team 		
	Abnormal bruising	<ul style="list-style-type: none"> • Repeat FBC and act on results as above 		
	Sore throat	<ul style="list-style-type: none"> • Repeat FBC and act on results as above 		
	Nausea and dizziness	<ul style="list-style-type: none"> • If possible continue, consider dose reduction or stop 		
	GI side effects	<ul style="list-style-type: none"> • Try symptomatic measures first 		

Gastroenterology Ipswich Hospital		Gastroenterology Colchester Hospital	
Dr Simon Williams 01473 703519	IBD Nurse Specialists Paula Salberg	Dr Ian Gooding Ian.Gooding@esneft.nhs.uk	IBD Nurse Specialists Kelly Turner
Dr Louise Scovell 01473 702535	Angela Curtis	Dr Mary McStay Mary.McStay@esneft.nhs.uk	Joy Mason
Dr Yin Miao 01473 703188	IBD Advice line 01473702865	Dr Simon Ralphs Simon.Ralphs@esneft.nhs.uk	01206 744231 (IBD Advice line) OR
Dr Abdul Mohsen 01473 703505	Email ihn-tr.Gastrosecs@nhs.net	Dr Achuth Shenoy Achuth.Shenoy@esneft.nhs.uk	07950542313 (IBD CNS Mobile)
Dr Hermant Laxaman 01473 703439	Advice and guidance on NHS e-referrals		