

SHARED CARE ARRANGEMENT AND PRESCRIBING INFORMATION FOR MERCAPTOPYRINE (ADULTS ONLY, NON-RENAL)



Note: This document should be read in conjunction with the current Summary of Product Characteristics (SmPC).

Patient safety is paramount. The prescriber who prescribes the medicine legally assumes clinical responsibility for the drug and the consequences of its use.

GENERIC AND BRAND NAME (formulations and strength)

Name: Mercaptopurine

Formulation: Tablets

Strength: 50mg

STATUS OF MEDICINE

Licence status: Licensed

Formulary status: Formulary

Black triangle medicine: NO

Risk minimisation materials (RMM): NO

CONDITION(S) TO BE TREATED

Moderate to severe crohn's disease or steroid resistant ulcerative colitis.

Mercaptopurine (6-MP) is used as a steroid-sparing agent in both ulcerative colitis and crohn's disease. It is an effective treatment in the management of inflammatory bowel disease to induce and maintain remission in patients intolerant of azathioprine. Mercaptopurine is the active metabolite of azathioprine.

TYPICAL DOSAGE REGIME

Licensed dose	See Gastroenterology Specialist for advice
Route of administration	Oral
Recommended starting dose	See Gastroenterology Specialist for advice
Titration dose/increment	See Gastroenterology Specialist for advice
Maximum dose	See Gastroenterology Specialist for advice
Situations requiring dose adjustment	See Gastroenterology Specialist for advice and Monitoring Schedule for DMARDs (refer to azathioprine information re monitoring)
Duration of treatment	See Gastroenterology Specialist for advice

RESPONSIBILITY OF ACUTE CARE/SPECIALIST SERVICE

- Baseline:
 - Full Blood Count (FBC)
 - Liver Function Tests (LFT), U&Es and creatinine
 - thiopurine S-methyltransferase (TPMT), Hep B core antibody, Hepatitis C, HIV and EBV as indicated
- Patients should be asked about the presence of sore throat, abnormal bruising or bleeding at each visit.
- Copy of baseline results to be shared with primary care.
- Mercaptopurine induced myelosuppression is linked to thiopurine methyl-transferase (TPMT) deficiency therefore the consultant will test for this prior to initiation of treatment.
- Initiation of therapy and recommendations for dose increments. This will be recommended by the Gastroenterology Department.
- A single dose of pneumococcal polysaccharide vaccine and annual influenza vaccine should be given; patients should be referred to receive these vaccines in accordance with [local protocol](#).

RESPONSIBILITY OF PRIMARY CARE

A Practice agreeing to prescribe Mercaptopurine should:

- Prescribe medication under the guidance of the Gastroenterology Consultant.
- The General Practitioner (GP) has primary responsibility for monitoring according to the [Monitoring Schedule for DMARDs](#) (Azathioprine Information). **Note:** Mercaptopurine is not listed on the Monitoring Schedule for DMARDs, however mercaptopurine is the active metabolite of azathioprine and as such the monitoring schedule for azathioprine should be followed for patients prescribed mercaptopurine.
- Patients should be asked about the presence of sore throat, abnormal bruising or bleeding at each visit.
- Ensure the GP is aware that the drug can cause:
 - Bone marrow suppression
 - Leucopenia
 - Increased risk of malignancy - lymphomas and skin cancer
- Ensure that the relevant monitoring requirements have been undertaken at the correct [frequency](#) (Azathioprine information).
- Ensure when the patient has an inter-current illness FBC, U+E and LFTs are done and make sure abnormal results are acted upon promptly.
- Only continue to prescribe medication if it is being satisfactorily monitored.
- Contact the Gastroenterology Department in the event of a drug reaction, monitoring abnormality, or if you are concerned in any way regarding the current treatment regime.
- Be alert for any of the known adverse reactions.
- The patient should be encouraged to ensure blood tests are undertaken at the correct intervals.
- It is responsibility of primary care to ensure that the medication is recorded on the patient's clinical medication record. This will facilitate central searches for annual vaccinations in order to ensure patients receiving DMARDs are called yearly by the HSCP teams for required vaccinations.

CARE WHICH IS THE RESPONSIBILITY OF THE PRESCRIBING CLINICIAN

- Prescribe medication under guidance of the Gastroenterology Consultant.
- Check before prescribing each instalment of medication that the monitoring is up to date and that results are within the normal range.
- Ensure no interacting medications are prescribed in primary care.
- Monitor for concordance with therapy.
- Report any adverse events to consultant and the MHRA using the Yellow Card System.
- If an intercurrent illness occurs, when writing laboratory request forms always include details of the patient' medication.
- If bloods are taken due to intercurrent illness, ensure they are monitored and contact hospital consultant to advise if results are out with range.
- A single dose of pneumococcal polysaccharide vaccine and annual influenza vaccine should be given, patients should be referred to receive these vaccines in accordance with local protocol.
- Varicella Zoster Immunoglobulin should be given to non-immune individuals if exposed to shingles or chickenpox. Patients should be referred in accordance with [local protocol](#).

Note: In addition to absolute values for haematological or biochemical indices a rapid change or a consistent upward/downward trend in any value should prompt caution and extra vigilance. If something unexpected occurs contact the Gastroenterology Department. Notify the Gastroenterology Consultant if the drug is stopped.

MONITORING

Refer to the [NHSG Guidelines For The Monitoring of Disease Modifying Anti-Rheumatic Drugs \(DMARDs\) For Healthcare Professionals](#). Results should be reviewed and action taken as per monitoring guidance. **Note:** Mercaptopurine is not listed on the Monitoring Schedule for DMARDs, however mercaptopurine is the active metabolite of azathioprine and as such the monitoring schedule for azathioprine should be followed for patients prescribed mercaptopurine. Mercaptopurine is included in the High Risk Local Enhanced Service (LES).

RESPONSIBILITY OF OTHER HEALTHCARE PROFESSIONALS

N/A.

RESPONSIBILITY OF THE PATIENT

- Take the medication regularly as directed by the specialist/doctor.
- Attend hospital and GP clinic appointments as requested by specialist/GP practice. Failure to attend appointments may result in medication being reviewed/stopped.
- Report any adverse effects/illness to the specialist/GP and present rapidly to specialist/GP should their condition significantly worsen.
- To minimise the risk of skin cancer, exposure to sunlight and ultra violet light should be limited by wearing protective clothing and using sunscreen with a high protection factor.
- The patient should ensure all blood tests are undertaken at the correct intervals.

PRESCRIBING INFORMATION

For specific product information consult the current summary of product characteristics (<http://emc.medicines.org.uk/>), the BNF/BNF for Children [Digital Medicines Information Suite | MedicinesComplete](#)

CONTRAINDICATIONS

- Hypersensitivity to azathioprine, 6-mercaptopurine (metabolite of azathioprine) or to any excipients listed in the SmPC.
- Severe infections.
- Seriously impaired hepatic or bone marrow.
- Pancreatitis.
- Any live vaccines; especially BCG, smallpox, yellow fever.

PREGNANCY

Further discussion is required with the Gastroenterology Specialist. Mercaptopurine should not be given to patients who are pregnant or likely to become pregnant without careful assessment of risk versus benefit. Should pregnancy occur during treatment this should be discussed with this with the relevant specialist service as soon as possible.

BREAST-FEEDING

The risk/benefit should be considered in lactating women. Mercaptopurine metabolites are undetectable or have been detected in small amounts (nanomolar concentrations of methylmercaptopurine and thiouric acid) in breast milk. Metabolites are undetectable in the few neonates studied, hence it is acceptable to advise that women can breast feed whilst continuing mercaptopurine. Further discussion with specialist service is recommended.

COMMON SIDE EFFECTS AND THEIR MANAGEMENT

- Nausea
- Diarrhoea
- Vomiting
- Anorexia
- Abdominal discomfort
- Headaches
- Pancreatitis

Action abnormal monitoring results are per [NHSG Disease Modifying Anti-Rheumatic Drugs \(DMARDs\) Monitoring Guidance](#). **Note:** Mercaptopurine is not listed on the Monitoring Schedule for DMARDs, however mercaptopurine is the active metabolite of azathioprine and as such the monitoring schedule/abnormal results monitoring actions for azathioprine should be followed for patients prescribed mercaptopurine.

The Gastroenterology Department should be contacted if there are any patient specific issues or concerns regarding side effects or abnormal results.

COMMON DRUG INTERACTIONS (for a full list see SmPC)

- Live vaccines should be avoided in patients taking mercaptopurine.
- Do not prescribe with Allopurinol (unless discussed/advised by a Gastroenterology Consultant).
- Inhibition of the anticoagulant effect of warfarin, when administered with mercaptopurine has been reported. Monitor concurrent use.
- Increased risk of haematological toxicity with co-trimoxazole and trimethoprim.

ADVERSE DRUG REPORTING

If an adverse reaction should occur inform relevant medical practitioner as soon as possible.


Report to the MHRA using the Yellow Card System <https://yellowcard.mhra.gov.uk/>

REFERENCES

- <https://www.medicines.org.uk/emc/product/10387/smpc>
- <https://www.formulary.nhs.scot/media/1392/sca-mercaptopurine.pdf>
- www.thurrockccg.nhs.uk/about-us/document-library/medicines-management/shared-care-guidelines/3258-shared-care-guideline-for-6-mercaptopurine/file

ACUTE CARE/SPECIALIST SERVICE CONTACT INFORMATION

In the event of a concern being raised, the primary care practitioner should contact the referring consultant via the hospital switchboard, via their secretary, by email or letter, whichever is more appropriate. If the concern is urgent, and out of hours advice is required, the Gastroenterology Department may be contacted via switchboard.

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