SHARED CARE ARRANGEMENT AND PRESCRIBING INFORMATION FOR MERCAPTOPURINE TABLETS (ADULTS)

This SCA is applicable for ALL conditions/specialities.

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 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 UNDER THIS SCA

Mercaptopurine is the active metabolite of azathioprine.

- Mercaptopurine (6-MP) is used as a steroid-sparing agent in both ulcerative colitis and Crohn's disease.
- Mecaptoputine is an effective treatment in the management of inflammatory bowel disease to induce and maintain remission in patients intolerant of azathioprine.
- Moderate to severe Crohn's disease or steroid resistant ulcerative colitis.

TYPICAL DOSAGE REGIME	
Licensed dose	See Specialist service for advice
Route of administration	Oral
Recommended starting dose	See Specialist service for advice
Titration dose/increment	See Specialist service for advice
Maximum dose	See Specialist service for advice
Situations requiring dose adjustment	See Specialist service for advice and Monitoring Schedule for DMARDs
Duration of treatment	See Specialist service for advice

RESPONSIBILITY OF ACUTE CARE/SPECIALIST SERVICE

- Baseline as per Monitoring Schedule for DMARDs:
  - Full Blood Count (FBC), Liver Function Tests (LFTs), and Urea and Electrolytes (U&Es)
  - Thiopurine S-methyltransferase (TPMT). Mercaptopurine induced myelosuppression is linked to thiopurine methyl-transferase (TPMT) deficiency therefore the consultant will test for this prior to initiation of treatment.

  Any additional tests, e.g. Hep B core antibody, Hepatitis C, HIV and EBV as indicated, determined by specialist service.
- Copy of baseline results to be shared with primary care.
- Request for initiation of therapy and recommendations for dose increments to Primary Care.
- Monitoring clinical response to treatment and advising on final dose required for the patient.
- Pneumococcal polysaccharide vaccine (PPV), COVID-19 vaccine and annual influenza vaccine should be given as per Joint Committee of Vaccination and Immunisation (JCVI)/The Green Book recommendations. Shingles vaccine should be given to those individuals who are severely immunocompromised, or anticipating immunosuppressive therapy, and eligible in line with JCVI/The Green Book recommendations and Scottish Government vaccination programme. Patients should be referred by specialist services to receive these vaccines in accordance with local protocol.
- Provide counselling, as appropriate, regarding pregnancy and breastfeeding.

RESPONSIBILITY OF PRIMARY CARE/PRESCRIBING CLINICIAN

A Practice agreeing to prescribe mercaptopurine should:

- Prescribe medication under the guidance of the consultant from the specialist service.
- Checking before prescribing each instalment of medication that the monitoring is up to date and that results are within a satisfactory range.
- Note: for individuals referred for vaccinations by the specialist service it is ideal to wait for vaccinations before starting immunosuppressive treatments. However this risks not controlling the autoimmune condition quickly which can negatively affect long term prognosis. Therefore specialties do not insist on a delay in starting immunosuppressive treatment to allow for vaccinations and recommend vaccinations happen as soon as possible after starting immunosuppressive treatment.
- Ensure that the relevant monitoring requirements have been undertaken at the correct frequency.
- The Practice/General Practitioner (GP) has primary responsibility for monitoring according to the Monitoring Schedule for DMARDs and review of results.
- Only continue to prescribe medication if it is being satisfactorily monitored.
- Ensure the GP is aware that the drug can cause:
  - Bone marrow suppression
  - Leucopenia
  - Increased risk of malignancy
  - Lymphomas and skin cancer
- Patients should be asked about the presence of sore throat, abnormal bruising or bleeding at each visit.
- Ensure when the patient has an inter-current illness FBC, U+E and LFTs are done and abnormal results are acted upon promptly. If an intercurrent illness occurs, when completing laboratory request always include details of the patient's medication.

- If bloods are taken due to intercurrent illness, ensure they are monitored and action taken as per the Monitoring Schedule for DMARDs.
- Infection - During a serious infection mercaptopurine should be temporarily discontinued until the patient has recovered from the infection and is off antibiotics for 2 weeks with no recurrence of infection.
  It can be considered appropriate to continue these drugs in patients with minor or uncomplicated viral infections or, if deemed clinically appropriate by the Specialist, in patients requiring long term antibiotic prophylaxis e.g. for prevention of recurrent UTIs.
- Contact the consultant 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.
- Ensure no interacting medications are prescribed in primary care.
- Monitor for concordance with therapy.
- 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 vaccinations in order to ensure patients receiving immunosuppressants are called by the HSCP teams for required vaccinations, e.g. influenza and covid programmes.
- Report any adverse events to consultant and the MHRA using the Yellow Card System.
- Post exposure prophylaxis (PEP) should be considered in non-immune individuals if exposed to shingles or chickenpox as per The Green Book.
- If something unexpected occurs contact consultant for the appropriate speciality.
- Notify consultant/specialist service if 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.

Primary Care are responsible to ensure results are reviewed and action taken as per monitoring guidance.

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.

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.
- The patient should ensure all blood tests are undertaken at the correct intervals.
- 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 (minimum SPF 30).

PRESCRIBING INFORMATION

For specific product information consult the current summary of product characteristics (http://emc.medicines.org.uk/), the BNF/BNF for Children BNF (British National Formulary) | NICE

CONTRAINDICATIONS

- Hypersensitivity to azathioprine, 6-mercaptopurine (metabolite of azathioprine) or to any excipients listed in the SmPC.
- Severe infections - during a serious infection mercaptopurine should be temporarily discontinued until the patient has recovered from the infection and is off antibiotics for 2 weeks with no recurrence of infection.
- Seriously impaired hepatic or bone marrow.
- Pancreatitis.
- It is recommended patients do not receive any live vaccines, especially BCG, smallpox, yellow fever until at least 3 months after the end of mercaptopurine treatment.

PREGNANCY

British Society for Rheumatology Guideline on prescribing drugs in pregnancy and breastfeeding: immunomodulatory anti-rheumatic drugs and corticosteroids from April 2023 states that azathiprine is safe in pregnancy and can be continued. Mercaptopurine is the active metabolite of azathioprine, this information is therefore considered applicable.

Women on mercaptopurine should be advised to adhere to their usual mercaptopurine monitoring, however no additional monitoring/change of therapy is required.

BREAST-FEEDING

British Society for Rheumatology Guideline on prescribing drugs in pregnancy and breastfeeding: immunomodulatory anti-rheumatic drugs and corticosteroids from April 2023 states that azathioprine is safe in breastfeeding (in a healthy, full term infant). Mercaptopurine is the active metabolite of azathioprine, this information it therefore considered applicable. This is outwith the product license which states patients should avoid breastfeeding while taking this medicine, but supported by specialist services.

COMMON SIDE EFFECTS

- Nausea
- Diarrhoea
- Vomiting
- Anorexia
- Abdominal discomfort
- Headaches
- Pancreatitis
- Mutagenicity and carcinogenicity increased risk of developing lymphoproliferative disorders and other malignancies, notably skin cancers (melanoma and non-melanoma) sarcomas (Kaposi's and non-Kaposi's) and uterine cervical cancer in situ
- Macrophage activation syndrome
- Patients with NUDT15 variant gene are at increased risk for severe 6-mercaptopurine toxicity such as early leucopenia and alopecia, from conventional doses of thiopurine therapy.
- Viral, fungal, and bacterial infections increased sensitivity to infection in patients with inflammatory bowel disease. Discuss severe infection with appropriate specialist service.

Action abnormal monitoring results are per NHSG Disease Modifying Anti-Rheumatic Drugs (DMARDs) Monitoring Guidance.

The Specialist service 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 azathioprine.
- Co-trimoxazole/trimethoprim - increased risk of haematological toxicity.
- Allopurinol - do not prescribe (unless discussed/advised by a Renal Consultant).
- Warfarin - monitor concurrent use. Inhibition of the anticoagulant effect of warfarin, when administered with azathioprine/mercaptopurine has been reported.

This information is not intended to be a complete list of interactions. For further information consider appropriate reference sources such as SmPC/Vision system.

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

- Search Results - (emc)
- British Society for Rheumatology Guideline

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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