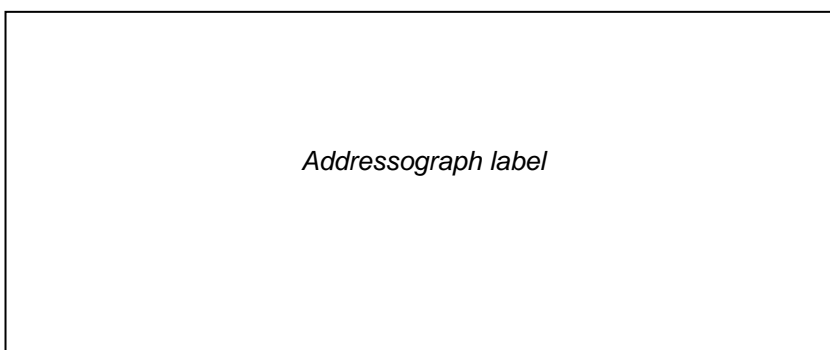


Further copies can be obtained from:

Pharmacy Department, Great Western Hospital  
NHS Wiltshire



**Patient's Name** \_\_\_\_\_

**Consultant Name** \_\_\_\_\_

**Consultant Signature** \_\_\_\_\_

**Date** \_\_\_\_\_

**I agree to your request to prescribe Azathioprine/Mercaptopurine in accordance with the attached shared care guideline:**

**GP Name** \_\_\_\_\_

**GP Practice Address** \_\_\_\_\_  
(if not on patient label)

**GP Signature** \_\_\_\_\_

**Date** \_\_\_\_\_

# Azathioprine/Mercaptopurine Tablets (TLS Amber)

(Please see list of indications covered by this shared care guideline on page 3)

## AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines how responsibility for prescribing azathioprine/mercaptopurine tablets might be shared between specialist and general practitioner (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as possible.

Sharing of care assumes communication between the specialist team, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes this medication legally assumes clinical responsibility for azathioprine/mercaptopurine tablets and the consequences of its use. Azathioprine/Mercaptopurine are indicated but not licensed for use in inflammatory bowel disease and autoimmune hepatitis, and hence are used in an off-label manner.

## RESPONSIBILITIES and ROLES

<b>Specialist team responsibilities</b>	
1	Initiate treatment, prescribe at least the first two months' supply of medication, and monitor the patient during this period.
2	Do baseline assessment pre-treatment (see page 3 for details).
3	Discuss the benefits and side effects of treatment with the patient and emphasise the importance of regular monitoring. Patients should be told to immediately report any signs or symptoms of bone marrow suppression (bleeding/bruising etc).
4	Ask the GP whether he or she is willing to participate in shared care, and discuss the shared care arrangement with the patient & obtain their consent.
5	Ensure compatibility of azathioprine/mercaptopurine with other concomitant medication. Check TPMT level.
6	Supply GP with clinic letter or discharge letter within 14 days of a hospital out-patient review or in-patient stay.
7	Review the patient's condition and monitor response to treatment at least annually or as deemed clinically necessary.
8	Give advice to the GP concerning ongoing prescribing, monitoring, dosage adjustments and when to stop treatment.
9	Report adverse events to the MHRA & GP.
10	Ensure clear backup arrangements exist for GPs to obtain additional advice and support should they need it.
<b>General Practitioner responsibilities</b>	
1	Reply to the request for shared care as soon as possible.
2	Prescribe medicine at the dose recommended by the specialist.
3	Undertake monitoring as per monitoring schedule on page 3 with particular reference to leucopenia.
4	Ensure compatibility of azathioprine/mercaptopurine with other concomitant medication.
5	Refer promptly to specialist team when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms suggestive of disease recurrence or progression) or intolerance to therapy occurs.
6	Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment.
7	Stop treatment on the advice of the specialist.
8	Report adverse events to the specialist and MHRA.
<b>Patient's role</b>	
1	Attend all appointments with GP and specialist, including appointments for blood tests and other monitoring.
2	Report to the specialist or GP if the patient does not have a clear understanding of the treatment.
3	Share any concerns in relation to treatment with medicine.
4	Inform specialist or GP of any other medication being taken, including over-the-counter products.
5	Report any adverse effects to the specialist or GP whilst taking the medicine.
6	Store the medicines safely, out of the reach of children and vulnerable people.

**BACK-UP ADVICE AND SUPPORT**

Contact Details	Telephone Number	E-mail Address
Gastroenterology Drug Monitoring Helpline	01793 607402	gastro.prescription@gwh.nhs.uk
The drug monitoring helpline utilises an answer machine and will be responded to within 24 hours Monday to Friday		

**SUPPORTING INFORMATION****Indications**

- Ulcerative colitis (unlicensed)
- Crohn's disease (unlicensed)
- Autoimmune hepatitis

**Pre-Treatment Assessment will include**

- Full blood count
- U+E's
- LFT's
- Hepatitis B and C
- HIV
- EBV
- Varicella serology

**Dosage and administration**

- The usual once daily dose of Azathioprine is 2-2.5mg/kg/day and Mercaptopurine is 1-1.5mg/kg/day for IBD and Azathioprine 1-1.5mg/kg/day and Mercaptopurine 1mg/kg/day for autoimmune hepatitis. The dose should be adjusted based on clinical response and haematological tolerance.
- Administer with or immediately after food.
- Therapeutic effect may only be evident after several weeks of treatment

**Contra-indications and precautions for use**

- Hypersensitivity to azathioprine or any of the excipients.
- Limit exposure to sunlight & UV light, patients should wear protective clothing and high factor sunscreen
- In patients with renal or hepatic insufficiency doses should be at the lower end of normal range.

**Side-effects**

Nausea when first starting treatment can be relieved by administering with food.

Please note: A raised MCV is common and not a reason to stop treatment

Very Common	Leucopenia, depression of bone marrow function
Common	Thrombocytopenia
Uncommon	Viral, fungal & bacterial infections, anaemia, pancreatitis, hypersensitivity reactions, Cholestasis & degeneration of liver function tests
Rare	Agranulocytosis, pancytopenia, aplastic anaemia, megaloblastic anaemia, colitis, Erythroid hypoplasia, alopecia, photosensitivity, neoplasms
Very Rare	Reversible pneumonitis, Stevens-Johnson Syndrome & toxic epidermal necrolysis

Please note that the following convention has been used for the classification of side-effects: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $<1/10$ ), uncommon ( $\geq 1/1,000$  to  $<1/100$ ), rare ( $\geq 1/10,000$  to  $<1/1000$ ) and very rare ( $<1/10,000$ ).

Refer patient back to the specialist if any of these side-effects cause concern. Refer to the SPC for a full list of adverse effects & further information <http://www.medicines.org.uk>.

*This medicine does not have black triangle (▼) status. Serious suspected reactions (even if well recognised or causal link uncertain) should be reported to the MHRA.*

## Monitoring

Parameter	Frequency of monitoring	Action
Full Blood Count: WCC <3.5; Neutrophils <1.5	Every 2 weeks for first 8 weeks Then again after a further 4 weeks Then every 3 months	If new fall below normal range or consistent downward trend - refer to helpline
Liver Function Tests: ALT or AST twice the upper limit of normal; abnormal alkaline phosphatase or bilirubin	As above	Refer to helpline
U+E	Every 6 months	If worsening trend, refer to helpline

## Drug Interactions

- Allopurinol/Oxipurinol/Thiopurinol – inhibits the metabolism of azathioprine. The dose of azathioprine must be reduced to 25% of the dose
- Warfarin – inhibition of anticoagulant effect may occur
- Live vaccines are contraindicated. Killed vaccines – diminished response may be seen
- Trimethoprim potentiates Azathioprine

See SPC for full list of interactions.

## References

- Electronic Medicines Compendium. Summary of Product Characteristics. Imuran Tablets (Azathioprine)

<http://www.medicines.org.uk/EMC/medicine/2881/SPC/Imuran+Tablets+25mg/>

- Electronic Medicines Compendium. Summary of Product Characteristics. Mercaptopurine Tablets

<http://www.medicines.org.uk/EMC/medicine/2881/SPC/mercaptopurine+50+mg+tablets>

BNF 66, September 2013 - March 2014

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**Date written:** January 2016

**Date of review:** January 2019