## Azathioprine and mercaptopurine for patients within adult services

|  |  |  |  |
| --- | --- | --- | --- |
| Version: | HNY v1.0 | Replaces version: | RDTC v1.2 |
| Clinical content last reviewed: | October 2023 | Next review date: | October 2025 |

|  |  |  |
| --- | --- | --- |
| **Version** | **Date published** | **Changes since previous version** |
| RDTC v1.0 | 7th December 2023 | Licensed indications updated to reflect currently available products. Interaction with leflunomide added. Advice on use in pregnancy amended to reflect current BSR guidance. Advice on shingles vaccination updated to reflect changes to schedule. Hyperlinks and references updated to current versions. |
| RDTC v1.1 | 8th March 2024 | * Section 8: corrected a broken hyperlink to the interactions section * Section 5: added HPV as a vaccine to consider prior to starting treatment * Section 6: added information on shingles vaccination for those aged 50 and older receiving immunosuppressive doses of AZA or 6MP. * Section 8: updated wording on live vaccination to emphasise low risk at low doses. * Added note to section 12 that cessation of treatment can result in disease flare and affect pregnancy outcome. |
| RDTC v1.2 | 26th November 2024 | * Advice on shingles vaccine clarified to reflect potential eligibility of patients aged 50 years or older taking immunosuppressive therapy |
| HNY v1.0 | April 2025 | * HNY logos added * Section 2: Vasculitis added to indications * Section 4: Transfer of monitoring and prescribing updated as per NHSE document - <https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf> and following wording added: To transfer from the specialist to primary care, the patient must be a) stable, i.e. the condition/indication is 'managed' appropriately, monitoring is within normal parameters, and b) the patient remains on the same dose that the specialist recommended. * Section 5: Creatinine clearance removed and replaced with eGFR * Section 5: Wording re screening for viral infections changed from "as per local policy" to "at discretion of the treating clinician" * Section 5: Wording re checking bloods after dose change amended from "every 2 weeks" to "repeat bloods after 2 weeks and 6 weeks" * Section 5: Ongoing monitoring – added " At initiation of shared care, communication to primary care should include current and ongoing dose, any relevant test results, and date the next monitoring is required." * Section 6: CrCl removed and added eGFR * Section 6: Removed monitoring of CRP & / or ESR * Section 6: Removed monitoring of bloods monthly for 3 months as this is responsibility of specialist (section 5) * Section 10: FBC management section – changed wording from "interruption" to "withholding treatment" * Section 10: Changed eosinophilia to unexplained eosinophilia * Section 10: Mean cell volume greater than 105fl – changed wording in management section from "Consider interruption in treatment if there is a significant increase from baseline" to " Check serum folate, B12, alcohol history and TSH and treat any underlying abnormality. If results of these additional investigations are abnormal treat, if normal discuss with specialist team" * Section 10: Management of signs or symptoms of bone marrow suppression – wording changed from "interruption in" to "withholding" * Section 10: Changed "calculated GFR" to eGFR * Section 10: Changed wording in management section from "Withhold and discuss with specialist team" to "discuss urgently with specialist team" * Section 11: Hyperlink to UKHSA guidance updated to most recent version * Section 13: Contact information updated to "Detailsfor contacting specialist must be included on clinic letter" * Section 15: Hyperlinks updated; removed Hanixol 50mg tablets as no longer listed on medicines.org website * Section 16: Hyperlink to Shared Care for Medicines Guidance updated |

**Local review and adoption**

|  |  |
| --- | --- |
| **Local approval** | **Date** |
| Local content added | March 2025 |
| Approved for use by Humber and North Yorkshire ICB | 2nd April 2025 |

Clinical content has been reviewed and updated by the RDTC on the date indicated above. Every effort is made to keep the content up to date. These templates are provided to the North West and North East and Yorkshire ICBs for localisation and approval through standard ICB processes. The most recent version is available on the RDTC website at <https://rdtc.nhs.uk/publication-type/shared-care/>.

This document is intended for use by NHS healthcare professionals and cannot be used for commercial or marketing purposes.

**Shared Care Protocol**

## Azathioprine and mercaptopurine for patients within adult services (non-transplant indications)

|  |  |
| --- | --- |
| Background | Azathioprine and mercaptopurine are disease modifying anti-rheumatic drugs (DMARDs). They are used as immunosuppressant anti-metabolites either alone or, more commonly, in combination with other agents (usually corticosteroids) to influence the immune response. Therapeutic effect may be evident only after weeks or months and can include a steroid sparing effect, thereby reducing the toxicity associated with high dosage and prolonged usage of corticosteroids.  Azathioprine and mercaptopurine are not licensed for all the conditions they are used to treat, as noted below. However, their use for the indications below are established and supported by various sources and bodies including the BNF, NICE, British Society for Rheumatology (BSR) and British Health Professionals in Rheumatology (BHPR), British Association of Dermatologists (BAD), British Thoracic Society (BTS), Association of British Neurologists (ABN) and British Society of Gastroenterology (BSG). |
| Licensed and agreed off-label indications | Azathioprine The licensed indications for azathioprine include:   * Auto-immune chronic active hepatitis * Auto-immune haemolytic anaemia * Behçet’s disease * Chronic refractory idiopathic thrombocytopenic purpura * Dermatomyositis * Inflammatory bowel disease (IBD) * Pemphigus vulgaris * Polyarteritis nodosa * Polymyositis * Pyoderma gangrenosum * Rheumatoid arthritis * Systemic lupus erythematosus (SLE)   Licensed indications vary with brand. See relevant [summary of product characteristics](https://www.medicines.org.uk/emc/search?q=azathioprine) (SPC) for full details.  This shared care protocol also includes treatment of chronic inflammatory conditions where off-label use of azathioprine is appropriate, including, but not limited to the following specialities and conditions:   * Dermatology (e.g. severe eczema) * Neurology (e.g. myasthenia gravis, demyelinating conditions) * Ophthalmology (e.g. uveitis, scleritis) * Oral medicine (e.g. refractory inflammatory oral disease) * Renal medicine (e.g. immune-mediated nephritis, vasculitis) * Respiratory disease (e.g. interstitial lung disease) * Rheumatology (e.g. inflammatory arthritis, connective tissue disease, vasculitis, giant cell arteritis)   These indications are off-label. The initiating specialist must specify the indication for each patient when initiating shared care and clearly state when use is off-label. Mercaptopurine This shared care protocol includes treatment of chronic inflammatory conditions where off-label use of mercaptopurine is appropriate, including, but not limited to the following conditions:   * Inflammatory bowel disease * Autoimmune encephalitides * Autoimmune hepatitis   These indications are off-label. The specialist must specify the indication for each patient when initiating shared care and clearly state when use is off-label.  This shared care protocol applies to adults aged 18 and over. It does not include use of azathioprine or mercaptopurine for transplant or oncology indications. |
| Locally agreed indications | As above |
| Initiation and ongoing dose regime | Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient’s dose has been optimised and with satisfactory investigation results for at least 12 weeks. To transfer from the specialist to primary care, the patient must be a) stable, i.e. the condition/indication is 'managed' appropriately, monitoring is within normal parameters, and b) the patient remains on the same dose that the specialist recommended.  The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.  All dose or formulation adjustments will be the responsibility of the specialist unless directions have been discussed and agreed with the primary care clinician.  Termination of treatment will be the responsibility of the specialist. Initial dosing: There is a wide dose range depending on the indication. The selected dose will be tailored to the individual patient and decided by the specialist.  **The initial stabilisation period must be prescribed by the initiating specialist.** Maintenance dose (following initial stabilisation): Usual dose range:   * Azathioprine: 0.5–3 mg/kg daily, adjusted according to response. * Mercaptopurine: 1-1.5mg/kg daily, adjusted according to response.   Some patients may respond to lower doses. Please note patients may be initiated on more than one DMARD.  **The initial maintenance dose must be prescribed by the initiating specialist.**  **Conditions requiring dose adjustment:**  Lower doses may be required if there is significant renal or hepatic impairment, in elderly patients, and in patients with mild/moderately impaired bone marrow function, TPMT deficiency or NUDT15 mutation ([see SPC)](https://www.medicines.org.uk/emc/search?q=azathioprine+or+mercaptopurine). |
| Baseline investigations, initial monitoring, and ongoing monitoring to be undertaken by specialist | Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in the immediate future will prescribing and monitoring be transferred to primary care. Baseline investigations:  * Height and weight * Blood pressure * Full blood count (FBC) * Urea and electrolytes (U&Es) & eGFR * Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST), and albumin * Baseline thiopurine methyl transferase (TPMT) status * Screening for viral infections at discretion of the treating clinician, e.g. HIV, hepatitis B and C, varicella zoster, Epstein Barr virus, cytomegalovirus * Screening for lung disease, including tuberculosis, should be undertaken at clinician discretion on a case-by-case basis * Confirm cervical screening is up to date * Provide or request appropriate vaccination prior to treatment initiation, according to local arrangements (e.g. pneumococcal, shingles, influenza, COVID-19, human papilloma virus)   Initial monitoring and at dose change:  To be repeated every 2 weeks until the dose has been stable for 6 weeks, then monthly for 3 months:   * FBC * U&Es, including creatinine and eGFR * LFTs, including AST and/or ALT, and albumin   Following a dose increase repeat bloods after 2 weeks and 6 weeks, then revert to previous schedule. More frequent monitoring is appropriate in patients at higher risk of toxicity. Ongoing monitoring: At initiation of shared care, communication to primary care should include current and ongoing dose, any relevant test results, and date the next monitoring is required.  The specialist will retain the responsibility for monitoring the patient’s ongoing response to treatment and advise if a dose change or treatment cessation is appropriate. This should usually be undertaken annually.  After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 6](#six_monitoring) remains appropriate. |

## Ongoing monitoring requirements to be undertaken by primary care

If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

| **Monitoring** | **Frequency** |
| --- | --- |
| * FBC * U&Es including creatinine and eGFR * ALT and/or AST, and albumin | After initial stabilisation, at least every 12 weeks, and more frequently in patients at higher risk of toxicity, as advised by the specialist team.  **The exact frequency of monitoring to be communicated by the specialist in all cases**. |
| * Patients aged 60-79 years old are eligible for the shingles vaccine (herpes zoster). Patients aged 50 years or older and taking immunosuppressive therapy may also be eligible. Specialist input may be required. Refer to [Green Book Chapter 6 (Contraindications and special considerations)](https://www.gov.uk/government/publications/contraindications-and-special-considerations-the-green-book-chapter-6) and [Green Book Chapter 28a (Shingles)](https://www.gov.uk/government/publications/shingles-herpes-zoster-the-green-book-chapter-28a) for further details. * **Annual** influenza ([The Green Book, Chapter 19](https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19)) vaccinations are recommended * COVID-19 vaccination is safe and recommended (see [Green Book Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)). * Repeat pneumococcal vaccine may be indicated. See [Green Book Chapter 25](https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25) for advice. | * Shingles vaccination: single course (two doses). * Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list. * COVID-19 vaccination as per national schedule. |

## Pharmaceutical aspects

|  |  |
| --- | --- |
| Route of administration: | Oral |
| Formulation: | Azathioprine 25mg and 50mg tablets  Azathioprine 10 mg/mL oral suspension (Jayempi®)  75mg and 100mg tablets are licensed but do not offer a clinical advantage and are high cost, and are therefore not preferred. Prescribers and dispensers should be aware of the risk of errors associated with these new strengths.  Mercaptopurine 50mg tablets  Mercaptopurine 20mg/ml oral suspension (Xaluprine®)  Mercaptopurine 10mg tablets (unlicensed import) |
| Administration details: | The tablets should be swallowed whole and not split / crushed.  Can be taken either with or without food, but patients should standardise which method is chosen. Tablets should be taken at least 1 hour before or 2 hours after milk or dairy products.  Taking with or after food may relieve nausea, however the oral absorption of azathioprine or mercaptopurine may be reduced. Consideration should be given to monitoring therapeutic efficacy more closely if patient is taking azathioprine or mercaptopurine consistently with food.  For azathioprine or mercaptopurine oral suspension, the bottle should be shaken vigorously for at least 30 seconds to ensure the suspension is well mixed. |
| Other important information: | Providing the film coating of azathioprine tablets remains intact, there is no risk or additional precautions required when handling tablets.  Azathioprine and mercaptopurine are cytotoxic. It is recommended that they are handled following local recommendations for the handling and disposal of cytotoxic agents.  Mercaptopurine tablets and oral suspension are not bioequivalent with respect to peak plasma concentration; increased haematological monitoring is advised if switching between formulations.  When prescribing mercaptopurine, remain vigilant with regards to the similarity in name with mercaptamine. |

|  |  |
| --- | --- |
| Cautions and contraindications | This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see [BNF](https://bnf.nice.org.uk/drugs/) & [SPC](https://www.medicines.org.uk/emc/search?q=azathioprine+or+mercaptopurine) for comprehensive information. Contraindications:  * Known hypersensitivity to the active substance or any excipients. Hypersensitivity to 6-mercaptopurine (6-MP) should alert the prescriber to probable hypersensitivity to azathioprine. * Absent or very low thiopurine methyltransferase (TPMT) activity – risk of life-threatening pancytopenia.  Cautions:  * Live vaccines (e.g. oral polio, oral typhoid, MMR, BCG,): are generally safe in patients taking azathioprine at a dose up to 3 mg/kg/day, or mercaptopurine up to 1.5 mg/kg/day. Please refer to the [Green Book Chapter 6](https://www.gov.uk/government/publications/contraindications-and-special-considerations-the-green-book-chapter-6) for current advice regarding the use of live vaccines in patients taking immune modulators. For yellow fever vaccination data is limited and a more cautious approach is advised – see [Green Book Chapter 35](https://www.gov.uk/government/publications/yellow-fever-the-green-book-chapter-35). Contact the specialist if further guidance is required. * Patients with active/history of pancreatitis. * Concomitant prescribing of allopurinol: A 75% dose reduction of azathioprine/mercaptopurine is required, see [section 9](#nine_interactions). * Patients receiving azathioprine or mercaptopurine are at an increased risk of developing lymphoproliferative disorders and other malignancies, notably skin cancers, sarcomas and uterine cervical cancer in situ. Exposure to sunlight and UV light should be limited and patients should wear protective clothing and use a sunscreen with a high protection factor to minimize the risk of skin cancer and photosensitivity * Patients with low thiopurine methyltransferase (TPMT) activity are at increased risk of myelosuppression. Substantial dose reduction is generally required. * Patients with inherited low or absent nudix hydrolase 15 (NUDT15) activity are at increased risk for azathioprine and mercaptopurine toxicity and generally require dose reduction. Genotype testing for NUDT15 mutation may be considered. Close monitoring of blood counts is necessary. * Severe infection. * Severely impaired hepatic or bone marrow function. * Pregnancy and breastfeeding (see [section 12](#twelve_pregnancy)).   Treatment may need to be monitored more frequently in the following:   * Elderly patients * Impaired renal function * Mild/moderately impaired hepatic function Mild/moderately impaired bone marrow function |
| Significant drug interactions | The following list is not exhaustive. Please see [BNF](https://bnf.nice.org.uk/drugs/) & [SPC](https://www.medicines.org.uk/emc/search?q=azathioprine+or+mercaptopurine) for comprehensive information and recommended management. The following drugs must not be prescribed without consultation with the specialist:  * **Allopurinol** has the potential to cause thiopurine toxicity and should be avoided, except with specialist input. Allopurinol may be recommended in combination with thiopurines by the specialist for IBD patients, particularly in those who are unable to tolerate to or do not respond to treatment with a thiopurine alone. The dose of azathioprine or mercaptopurine should be reduced by 75% if used concurrently with allopurinol. If considering prescribing allopurinol, discuss with the specialist for advice and a dose adjustment. * **Febuxostat** has the potential to cause thiopurine toxicity; avoid in combination with azathioprine or mercaptopurine. * **Live vaccines** (e.g. oral polio, oral typhoid, MMR, BCG,) can be given to patients on stable long term low dose corticosteroid therapy (defined as ≤20mg prednisolone per day for >14 days) alone or in combination with low dose non-biological oral immune modulating drugs (e.g. azathioprine up to 3mg/kg/day or mercaptopurine up to 1.5mg/kg/day). Clinician discretion is advised. Please refer to the [Green Book Chapter 6](https://www.gov.uk/government/publications/contraindications-and-special-considerations-the-green-book-chapter-6) for current advice, and advice for patients taking higher doses. * **Warfarin** – thiopurines may reduce anticoagulant effects of warfarin. * **Co-trimoxazole / trimethoprim** – possible increased risk of haematological toxicity, however evidence is conflicting and this combination is often used in practice. * **Clozapine** – avoid due to increased risk of agranulocytosis. * **Ribavirin** – increased risk of haematological toxicity when azathioprine given concurrently and this combination should be avoided. * **Aminosalicylates** (sulfasalazine, mesalazine or olsalazine) – increased risk of haematological toxicity with concomitant thiopurine due to TPMT inhibition. Dose adjustment of azathioprine or mercaptopurine and additional monitoring of FBC may be required. * **Leflunomide** – risk of myelosuppression.  The following drugs may be prescribed with caution:  * **ACE inhibitors** – increase the risk of anaemia and or leukopenia. * **Cimetidine and indomethacin** – concomitant administration of thiopurines may increase the risk of myelosuppression. |

## Adverse effects and management

As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance**.** For information on incidence of ADRs see relevant SPCs.

**Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit** [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

Advice based on shared care guidelines published by NHS England, and checked against current guidance.

| **Adverse effect** | **Management** |
| --- | --- |
| Full blood count:   * White blood cells less than 3.5x109/L * Lymphocytes less than 0.5x109/L * Neutrophils less than 1.6x109/L * Platelets less than 140x109/L * Unexplained Eosinophilia greater than 0.5x109/L | Discuss urgently with specialist team, and consider withholding treatment.  NB: Isolated lymphopenia or eosinophilia is often a feature of the underlying autoimmune indication, and is rarely an indication to discontinue azathioprine. |
| Mean cell volume greater than 105 fl  NB: Reversible, dose-related increases in mean corpuscular volume are a known effect of thiopurines. | Check serum folate, B12, alcohol history and TSH and treat any underlying abnormality. If results of these additional investigations are abnormal treat, if normal discuss with specialist team. |
| Signs or symptoms of bone marrow suppression, e.g. unexplained bleeding or bruising with or without sore throat, mouth ulcers | Consider withholding treatment. Check FBC immediately and discuss with the specialist team. See haematological monitoring above. |
| Infections:  Infection requiring antibiotics | Temporarily withhold thiopurine until the patient has recovered. Consider additional investigations (e.g. FBC), if clinically appropriate. |
| Liver function tests:  ALT or AST greater than 100 units/L, or any sudden increases (e.g. double of baseline), OR  Unexplained fall in serum albumin less than 30g/L  Jaundice | When used for hepatology indications, continue treatment and discuss with specialist urgently.  For all other indications, withhold and discuss with specialist team.  Check any other reason for risk of hepatic dysfunction such as alcohol history and drug interactions, including OTC or complementary medication. |
| Renal function:  Creatinine rise greater than 30% over 12 months, or eGFR reduces to less than 60ml/min | Discuss urgently with specialist team |
| Gastrointestinal disorders:  Nausea | Review for reversible causes. Advise patient to take with food. If no improvement contact specialist team. |
| Suspected pancreatitis | Withhold and discuss with specialist team. |

|  |  |
| --- | --- |
| Advice to patients and carers The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual drugs. | The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:  * Signs or symptoms indicating haematological toxicity, e.g. sore throat, infection, unexplained or abnormal bruising or bleeding. * Signs or symptoms of pancreatitis, e.g. abdominal pain, nausea, or vomiting. * Signs of symptoms of hepatic toxicity, e.g. Jaundice (yellowing of the skin or whites of the eyes).  The patient should be advised to:  * During a serious infection azathioprine or mercaptopurine should be temporarily discontinued until the patient has recovered from the infection. * That vaccination in line with current national advice (e.g. for COVID-19, influenza) is safe and recommended. * Tell anyone who prescribes them a medicine that they are taking azathioprine or mercaptopurine. Always ask a pharmacist before purchasing any medicines over the counter, including herbal remedies, and ask if they are safe. * To inform their specialist or primary care prescriber promptly if pregnancy occurs or is planned. * All women aged 25-64 years old should be encouraged to participate in national cervical cancer screening programmes. There is no need to attend more frequently than recommended. * Patients have a small increased risk of skin cancers so should be advised to wear high factor sunscreen and to wear a hat and protective clothing when in strong sunshine. Sun beds should be avoided. Patients should be advised to carry out regular self-examination of the skin and report if there are any new lesions and/or changes to skin. * Patients taking azathioprine at a dose of 3 mg/kg or more, or mercaptopurine at a dose of 1.5 mg/kg/day or more should be advised to avoid contact with people with chicken pox or shingles and report any such contact urgently to their primary care prescriber. If the patient is exposed, contact the specialist for advice. For detailed advice on risk assessment and post exposure prophylaxis following exposure to chicken pox and shingles, see:   + [the Green Book (Chapter 34)](https://www.gov.uk/government/publications/varicella-the-green-book-chapter-34)   + UKHSA guidance: [Guidelines on post exposure prophylaxis (PEP) for varicella and shingles](https://www.gov.uk/government/publications/post-exposure-prophylaxis-for-chickenpox-and-shingles) (February 2025)   Patient information:   * General information: [NHS.uk](https://www.nhs.uk/medicines/azathioprine/) * General information: [patient.info](https://patient.info/medicine/azathioprine-azapress-imuran) * Rheumatology: [Versus Arthritis](https://www.versusarthritis.org/about-arthritis/treatments/drugs/azathioprine/) * Dermatology: [British Association of Dermatologists](https://www.bad.org.uk/for-the-public/patient-information-leaflets/azathioprine) * Patient information leaflets are also available from the [electronic medicines compendium](https://www.medicines.org.uk/emc/)   Gastroenterology:   * [Crohns and Colitis UK](https://www.crohnsandcolitis.org.uk/about-crohns-and-colitis/publications/azathioprine-mercaptopurine) * <https://gutscharity.org.uk/advice-and-information/conditions/crohns-disease/> * [Guts UK - ulcerative colitis](https://gutscharity.org.uk/advice-and-information/conditions/ulcerative-colitis/) |
| Pregnancy, paternal exposure and breastfeeding | **All patients should be informed of the risks and benefits of taking this medicine during pregnancy and breastfeeding. The specialist team should be contacted if a patient becomes pregnant or is planning to become pregnant or breastfeed.** Pregnancy: The [BSR and BHPR guideline on prescribing DMARDs in pregnancy and breastfeeding](https://academic.oup.com/rheumatology/article/62/4/e48/6783012) advises that azathioprine is compatible throughout pregnancy.  Current available data do not suggest that mercaptopurine exposure during pregnancy increases the risk of miscarriage, congenital malformation, intrauterine death, fetal growth restriction, or preterm delivery but the data are limited for some outcomes. A careful assessment of risk versus benefit should be made before mercaptopurine is prescribed to patients who are pregnant. Cessation of treatment can result in disease flare which may increase the risk of poor pregnancy outcomes. Urgent discussion with the prescribing specialist is advised.  The [British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease](https://gut.bmj.com/content/68/Suppl_3/s1.long) advises that both maintenance and flares can be treated as normal with thiopurines (azathioprine and mercaptopurine) during pregnancy.   * Information for healthcare professionals: [UK Teratology Information Service](https://uktis.org/monographs/use-of-azathioprine-or-mercaptopurine-in-pregnancy/) * Information for patients and carers: [Best Use of Medicines in Pregnancy](https://www.medicinesinpregnancy.org/Medicine--pregnancy/Azathioprinemercaptopurine/)  Breastfeeding: Azathioprine is compatible with breastfeeding, although the active metabolite mercaptopurine is present in breast milk. A risk versus benefit assessment is advised. If used during breastfeeding, monitor for signs of infection or immunosuppression. If high doses of azathioprine are used, monitor infant blood counts. If mercaptopurine is used, monitor infant’s blood count and liver function.  Information for healthcare professionals:   * UK Drugs in Lactation Advisory Service - [azathioprine](https://www.sps.nhs.uk/medicines/azathioprine/) * UK Drugs in Lactation Advisory Service - [mercaptopurine](https://www.sps.nhs.uk/medicines/mercaptopurine/)  Paternal exposure: Azathioprine and mercaptopurine are compatible with paternal exposure and are not usually regarded as grounds for additional fetal monitoring. There is currently no evidence of adverse fetal effects relating to paternal use. Individual risk-benefit assessment is recommended.  Information for healthcare professionals: [UK Teratology Information Service - use of azathioprine or mercaptopurine](https://uktis.org/monographs/paternal-use-of-azathioprine-or-mercaptopurine/) |
| Specialist contact information and arrangements for referral | Details for contacting specialist must be included on the clinic letter*.* |
| Additional information | Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient’s GP or their contact details. |
| References | 1. British National Formulary accessed via <https://bnf.nice.org.uk/> on 20/10/2023. 2. Azathioprine 50mg tablets (Imuran®). Aspen. Date of revision of the text: May 2022. Accessed via <https://www.medicines.org.uk/emc/product/3823> on 20/10/2023. 3. Azathioprine Tablets 50mg. Mylan. Date of revision of the text October 2023. Accessed via <https://www.medicines.org.uk/emc/product/2541/smpc> on 20/10/2023. 4. Azathioprine tablets 50 mg. Strides Pharma. Date of revision of the text 20/06/2022. Accessed via <https://www.medicines.org.uk/emc/product/14296/smpc> on 20/10/2023. 5. Azathioprine 50mg Film-Coated Tablets. Tillomed Laboratories. Date of revision of the text: 18/07/2023. Accessed via <https://www.medicines.org.uk/emc/product/11143/smpc> on 20/10/2023. 6. Jayempi 10mg/ml oral suspension. Nova Laboratories. Date of revision of the text: 26/09/2023. Accessed via <https://www.medicines.org.uk/emc/product/12745/smpc> on 20/10/2023. 7. Mercaptopurine 50mg tablets. Aspen. Date of revision of the text: May2023. Accessed via <https://www.medicines.org.uk/emc/product/4655/smpc> on 20/10/2023. 8. Mercaptopurine 20mg/ml oral suspension (Xaluprine®). Nova Laboratories Ltd. Date of revision of the text: 25/05/2023. Accessed via <https://www.medicines.org.uk/emc/product/2949/smpc> on 20/10/2023. 9. British Society of Rheumatology and British Health Professionals in Rheumatology. 2017. [Guidelines for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs](https://academic.oup.com/rheumatology/article/56/6/865/3053478). Accessed 20/10/2023. 10. British Society for Rheumatology 2023. [Guideline on prescribing drugs in pregnancy and breastfeeding: immunomodulatory anti-rheumatic drugs and corticosteroids](https://academic.oup.com/rheumatology/article/62/4/e48/6783012). Accessed via <https://academic.oup.com/rheumatology/article/62/4/e48/6783012> on 20/10/2023. 11. British Association of Dermatologists. 2011. [Guidelines for the safe and effective prescribing of azathioprine](https://academic.oup.com/bjd/article/165/4/711/6644050?login=false). Accessed 01/10/2020. 12. British Association of Dermatologists. Azathioprine Patient Information Leaflet. September 2021 Accessed via <http://www.bad.org.uk/pils/azathioprine/> on 31/10/2023. 13. British Thoracic Society in collaboration with the Thoracic Society of Australia and New Zealand and the Irish Thoracic Society. 2008. [Interstitial lung disease guideline](https://www.brit-thoracic.org.uk/quality-improvement/guideline-archive/) (archived). Accessed 31/10/2023. 14. British Society of Gastroenterology. 2019. [Consensus guidelines on the management of inflammatory bowel disease in adults](https://www.bsg.org.uk/clinical-resource/bsg-consensus-guidelines-on-the-management-of-inflammatory-bowel-disease-in-adults/). Accessed 01/10/2020. 15. British Society of Gastroenterology. 2011. [Guidelines on the management of autoimmune hepatitis](https://www.bsg.org.uk/clinical-resource/bsg-guidelines-autoimmune-hepatitis). Accessed 01/10/2020. 16. Association of British Neurologists. 2015. [Myasthenia gravis: management guidelines](https://pn.bmj.com/content/practneurol/15/3/199.full.pdf). Accessed 31/10/2023. 17. Public Health England. [Immunisation against infections disease: The Green Book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book). Accessed 20/10/2023. 18. Specialist Pharmacy Service. Lactation Safety Information: azathioprine. Reviewed September 2020. Accessed via <https://www.sps.nhs.uk/medicines/azathioprine/> on 20/10/2023. 19. Specialist Pharmacy Service. Lactation Safety Information: mercaptopurine. Reviewed September 2020. Accessed via <https://www.sps.nhs.uk/medicines/mercaptopurine/> on 20/10/2023. 20. UK Teratology Information Service. Toxbase monograph: Azathioprine or mercaptopurine in pregnancy. December 2019. Accessed via [www.toxbase.org](http://www.toxbase.org/) on 20/10/2023. 21. UK Teratology Information Service. Toxbase monograph: Paternal use of azathioprine or mercaptopurine. December 2019. Accessed via [www.toxbase.org](http://www.toxbase.org/) on 20/10/2023. 22. The Renal Drug Database. Mercaptopurine monograph. Last reviewed 20/06/2018. Accessed via: <https://renaldrugdatabase.com/> on 20/10/23. 23. NICE Guidance: Crohn’s disease: management (NG129) May 2019. Accessed via: <https://www.nice.org.uk/guidance/ng129> on 20/10/23. 24. NICE Guidance: Ulcerative colitis: management (NG130) May 2019. Accessed via: <https://www.nice.org.uk/guidance/ng130> on 20/10/23. 25. Direct Healthcare Professional Communication. Azathioprine 75mg & 100mg tablets. Risk of overdose if wrong dose prescribed or dispensed. Accessed via <https://assets.publishing.service.gov.uk/media/653f920b80884d0013f71d34/Azathioprine.pdf> on 03/11/2023. 26. Specialist Pharmacy Service. Medicines Monitoring. Azathioprine. Last updated 20 September 2023. Accessed via <https://www.sps.nhs.uk/monitorings/azathioprine-monitoring/> on 04/12/2023. 27. Specialist Pharmacy Service. Medicines Monitoring. Mercaptopurine. Last updated 20 September 2023. Accessed via <https://www.sps.nhs.uk/monitorings/mercaptopurine-monitoring/> on 04/12/2023. |
| To be read in conjunction with the following documents | * Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from <https://www.medicinesresources.nhs.uk/shared-care-for-medicines-guidance-a-standard-approach-rmoc.html> * NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from <https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/> * General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care> * NICE NG197: Shared decision making. Last updated June 2021. <https://www.nice.org.uk/guidance/ng197/>. |