Disease Modifying Anti-rheumatic Drugs (DMARDs)

Disclaimer

This page provides basic information only. For full prescribing information, see clinical software.

DMARDs reduce joint damage and symptoms and allow steroid sparing. Early use is more effective in inducing remission and delaying disease progression. There is increasing evidence that appropriate use of DMARDs can improve a patient’s CVD risk profile by decreasing their systemic inflammatory state. They are often used in combination therapy, which is more effective but has higher toxicity.

DMARDs are generally prescribed by specialists and there are PBS restrictions on biologic DMARDs preventing their initiation by general practitioners. In some circumstances, it may be appropriate for GPs to start a DMARD, in consultation with a specialist, in primary care. GPs have an important role in shared management of patients on DMARDs.

Contents

Disclaimer .................................................................................................................................................. 1
Contradictions ........................................................................................................................................ 2
Pre-treatment Considerations .................................................................................................................. 2
Medications ................................................................................................................................................ 4
  Azathioprine (AZA) .................................................................................................................................. 4
  Cyclophosphamide (CTX) ....................................................................................................................... 5
  Cyclosporin (CSA) ................................................................................................................................. 6
  Gold (myocrisin) ..................................................................................................................................... 7
  Hydroxychloroquine (HCQ) .................................................................................................................. 7
  Leflunomide (LEF) ............................................................................................................................... 8
  Methotrexate (MTX) ............................................................................................................................. 9
  Sulphasalazine (SSZ) ............................................................................................................................ 10
  Biological DMARDS (bDMARDs) ......................................................................................................... 11
  JAK Inhibitors ........................................................................................................................................ 13
Information .................................................................................................................................................. 14
  For health professionals ........................................................................................................................ 14
  For patients ............................................................................................................................................ 14
References ................................................................................................................................................. 15
Disclaimer ................................................................................................................................................. 15
Contradictions

➢ Pregnancy:
   • Extra care must be taken in women of child-bearing age.
   • Some DMARDs are teratogens including cyclophosphamide, leflunomide, and methotrexate.
     ○ If unsure, seek rheumatology advice.
     ○ See also Guidance on Prescribing Medications for Rheumatic Diseases in Pregnancy.
   • Paternal exposure is likely to be safe. For advice about specific medications, see Guidance on Prescribing Medications for Rheumatic Diseases in Pregnancy.

➢ Concurrent use of live vaccines is contraindicated with most DMARDs – this has caused death. Appropriate non-live vaccinations are highly recommended.

Live vaccines
These include:
• MMR – the combination measles, mumps, and rubella vaccine.
• Varicella or chicken pox and Herpes Zoster.
• Proquad – a MMR and Varicella combination.
• Rotavirus – including two oral vaccines, RotaTeq and Rotarix, normally only recommended in infancy.
• Yellow fever – an attenuated, live-virus vaccine recommended for travellers to high risk areas.
• Typhoid – the oral typhoid vaccine is made with a live-attenuated strain of Salmonella typhi. An inactivated, injectable version of the vaccine is also available.
• BCG – the bacille Calmette-Guerin tuberculosis vaccine.
• Smallpox – has not been routinely used since 1972 but is available from stockpiles if it is needed.
• Oral polio – the original OPV (Sabin vaccine) is not available in Australia. Only inactivated injectable formulation available.

➢ See medications information for drug-specific contraindications and speak with a rheumatologist if unsure.

Pre-treatment Considerations

➢ Order baseline bloods and screening.

Baseline bloods and screening
• FBE
• E/LFT
• Screen for hepatitis B, hepatitis C, HIV, and tuberculosis

➢ Consider:
   • impact of any co-morbidities
Co-morbidities
- Liver failure
- Renal impairment
- Heart failure
- Malignancy or lymphoproliferative
- Multiple sclerosis (MS)
- COPD
- Bronchiectasis
- Interstitial lung disease
- Latent infection

➢ chest X-ray if background of respiratory risks.

Vaccination
- Live vaccines (e.g., zostavax) are contraindicated with many DMARDs.
- Ideally vaccinate before starting DMARDs or bDMARDS.
- Both auto-immune disease and the medications used may predispose to infection. Consider vaccination for all patients, as appropriate including:
  - Influenza (repeat annually).
  - Pneumococcal – a 3rd (privately funded) dose of the 23vPPV pneumococcal vaccine is recommended 5 years after the 2nd dose for patients with autoimmune inflammatory rheumatic diseases.
  - Varicella zoster – prior to immunosuppression only.
  - MMR – if have not had two documented doses, prior to immunosuppression only.
  - DTPa
  - Hepatitis B – for all patients prior to starting MTX
  - Hepatitis A and B, for other patients if at risk.
  - HPV in women aged < 25 years.
  - Rubella in women of childbearing age who are not immune on serology testing or have not had 2 documented doses of MMR, prior to immunosuppression only.
  - Meningococcal, Hib, if hyposplenia.

For more detailed information, see Internal Medicine Journal – A Practical Approach to Vaccination of Patients with Autoimmune Inflammatory Rheumatic Diseases in Australia.

See also Immunisation – Adults.

- Once therapy has commenced:
  - non-live vaccines can still be given but efficacy may be diminished.
  - live vaccines should not be given without expert advice.

- complications and serious adverse reactions including infections, marrow suppression, cancer, hepatotoxicity, and skin reactions.

➢ See medications information for drug-specific initiation protocols.
**Azathioprine (AZA)**

- **Indications** – rheumatoid arthritis, systemic lupus erythematosus, inflammatory bowel disease (IBD) and other auto-immune conditions.
- **Mode of action** – immunosuppressant (metabolised to 6-MP, a purine thioanalogue).

**Precautions and contraindications**
- **Contraindications:**
  - Known sensitivity.
  - Active serious infection.
  - Concurrent allopurinol or febuxostat use – unless with specialist management.

- Can be used in pregnancy at a dose not exceeding 2mg/kg/day
- Thiopurine methyl transferase (TPMT) deficiency leading to toxic levels of active azathioprine occurs in 1/250 and is associated with increased risks of myelosuppression.
- Avoid live vaccines.
- Warn patients about increased risk and severity of infections and of neoplasia e.g., skin cancer.
- Advise about UV protection and adequate contraception.
- Reduce dose in renal or hepatic impairment.
- Interactions include allopurinol, febuxostat, anticoagulants, angiotensin-converting enzyme inhibitors (ACE inhibitors), other immunosuppressants. See Patient Information in prescribing software.

**Initiation and dose**
- Initiated under specialist management at 1 mg/kg (50 mg) increasing to maximum 2.5 mg/kg, or lowest dose that achieves efficacy.
- Response may take 1 to 6 months.

**Side-effects**
- Common – gastrointestinal effects (try reduced or divided dose).
- Serious – includes cytopaenias, severe infections, renal and hepatic dysfunction, rash, pancreatitis, interstitial lung disease.

**Monitoring**
- Use a reminder system.
- Ask about side-effects especially infections, bleeding, or bruising.
- FBE, E/LFT every 2 weeks initially and with dose increases, then 3 monthly once stable.
- Annual specialist review.
- Cease azathioprine and seek [rheumatology advice](#) if:
  - abnormal blood count.
  - abnormal liver function
- Hypotension.
- Hypersensitivity (myalgia and fever).
- Malignancy.

- Ideally baseline bloods will have been done before initiation.

### Cyclophosphamide (CTX)

- Indications – third-line agent for auto-immune conditions.
- Mode of action – alkylating agent (immunosuppressant).

#### Precautions and contraindications
- Contraindications:
  - Known sensitivity.
  - Pregnancy or lactation.
  - Active infection.
  - Cystitis.

- Warn patients about increased risk and severity of both infections and neoplasia.
- Caution with live vaccines.
- Advise about UV protection and adequate contraception.
- Interactions are multiple, including digoxin, phenytoin, benzodiazepines, phenothiazines, and anaesthetic agents. See Patient Information in prescribing software.

#### Initiation and dose
- Initiated under specialist management at 50 to 250 mg daily.
- Response may take 6 to 12 weeks.

#### Side-effects
- Common – gastrointestinal effects.
- Serious – includes:
  - Cytopaenias.
  - Secondary neoplasia.
  - Severe infections.
  - Pigmentation.
  - Pulmonary fibrosis.
  - Haemorrhagic cystitis.
  - Alopecia.
  - Fluid retention.
  - Renal and hepatic dysfunction.
  - Interstitial lung disease.

#### Monitoring
- Use a reminder system.
- Ask about side-effects especially infections, cystitis, bleeding, or bruising.
- FBE, creatinine and electrolytes, and urinalysis every 2 weeks initially and then monthly.
- Regular specialist review.
- Cease cyclophosphamide and seek rheumatology advice if:
  - Abnormal blood count
- recurrent infections.
- intractable nausea.
- abnormal liver or renal function.
- malignancy.

- Ideally baseline bloods will have been done before initiation.

### Cyclosporin (CSA)

- **Indications** – rheumatoid arthritis, psoriasis.
- **Mode of action** – immunosuppressant.

#### Precautions and contraindications
- **Contraindications:**
  - Uncontrolled hypertension or infection.
  - Immunodeficiency.
  - Renal or hepatic dysfunction.
  - Previous or current malignancy.
  - Severe cardiovascular or pulmonary disease.
  - Pregnancy or lactation.

- Usually only under specialist management.
- Warn about increased risk of cancer including skin cancer and advise about UV protection.
- Avoid live vaccines.
- Multiple interactions – extreme care with any new change to medications. See Patient Information in prescribing software.

#### Initiation and dose
- Initiated under specialist advice at 3 mg/kg a day split as two doses.
- Titrated at 1-to 2-month intervals to a maximum of 5 mg/kg a day.
- Response may take 1 to 3 months.

#### Side-effects
- Common – hypertension, renal toxicity, anorexia and gastrointestinal upset, gum hyperplasia, tremor, paraesthesia, hirsutism, rash, myalgia, hyperglycaemia.
- Serious – includes hyperkalaemia, severe infections, hepatic and renal dysfunction, lipid abnormalities, cytopenias.

#### Monitoring
- Use a reminder system.
- Ask about side-effects especially infections, gastrointestinal effects, rash, and skin lesions.
- Blood pressure and creatinine every 2 weeks for first 3 months, then monthly.
- FBE, E/LFT, urinary protein every 3 months.
- Cease cyclosporin and seek **rheumatology advice** if:
  - hypertension occurs (start concurrent anti-hypertensives).
  - creatinine rise > 30% above baseline.
  - LFTs > x 2 upper limit of normal.
  - neutropaenia or thrombocytopaenia.
  - any serious event e.g., severe rash, infection, malignancy.

- Ideally baseline bloods will have been done before initiation.
Gold (myocrisin)

- Indications – rheumatoid arthritis, Still's disease.
- Mode of action – affects lysosomal function.

Precautions and contraindications
- Contraindications:
  - Severe renal or hepatic dysfunction.
  - Diabetes.
  - History of blood dyscrasias.
  - Pregnancy or lactation.
  - Inflammatory bowel disease (IBD).
  - Cardiac failure.
  - Chronic skin conditions.
  - Systemic lupus erythematosus (SLE).
- Interactions include penicillamine and angiotensin-converting enzyme inhibitors (ACE inhibitors). See Patient Information in prescribing software.

Initiation and dose
- Usually initiated under specialist advice at 10 mg intramuscular (IM) weekly, up-titrated gradually to 50 mg weekly.
- If effective after 14 to 20 weeks, down-titrated to fortnightly injections then monthly maintenance injections of 50 mg intramuscular (IM).
- Response may take 20 weeks.
- Now used infrequently and there is limited supply.

Side-effects
- Common – rashes, pruritus.
- Serious – rare. Includes severe rashes, nephrotoxicity, cytopaenias.

Monitoring
- Prior to each injection e.g., monthly.
- Ask about side effects – mouth ulcers, rash, itch, bleeding, and bruising.
- FBE, dipstick urine for protein.
- Cease gold and seek rheumatology advice if:
  - neutropenia or thrombocytopenia or eosinophilia.
  - proteinuria ≥ ++ on dipstick.
  - rash (pruritus may presage rash).
  - mouth ulcers (mild or moderate may respond to reduced dose).
  - lung or gastrointestinal complications.
- Ideally baseline bloods will have been done before initiation.

Hydroxychloroquine (HCQ)

- Indications – rheumatoid arthritis and lupus.
- Mode of action – not known.
Precautions and contraindications
- Cautions:
  - Can be used in pregnancy
  - Pre-existing retinal disease e.g., diabetic, age-related
  - G6PD deficiency
  - Psoriasis
  - Diabetes
  - Renal impairment
  - Concurrent Tamoxifen (can increase risk of retinal toxicity)
- Usually well tolerated – warn patient of main risk which is late retinopathy
- Rare hypoglycaemia.
- Many interactions have been reported including monoamine oxidase inhibitor (MAOI), digoxin, amiodarone, anti-diabetic agents, and amiodarone. See Patient Information in prescribing software.

Initiation and dose
- Usually initiated under specialist advice.
- Maintenance 200 to 400 mg a day – maximum 6.5 mg/kg.
- Response may take many months – requires at least a 6-month trial.

Side-effects
- Common – nausea (usually resolves with tolerance).
- Serious:
  - Rare progressive and irreversible ocular toxicity which is a dose-dependent risk over years.
  - Also, myopathy, photosensitivity, abnormal skin pigmentation, rashes or neuropathy may require drug cessation.
  - Hypoglycaemia and cytopaenia is rare.

Monitoring
- Ask about side-effects especially visual symptoms e.g., intolerance of glare, difficulty seeing entire words or faces, decreased night or peripheral vision.
- Regular ophthalmological review at baseline, then annually after 5 years.
- Cease HCQ and seek rheumatology advice if:
  - visual field corneal or macula abnormality.
  - blood dyscrasias or haemolytic anaemia.
  - QT prolongation or cardiac symptoms.

Leflunomide (LEF)
- Indications – rheumatoid arthritis and psoriatic arthritis.
- Mode of action – pyrimidine synthesis inhibitor, immunosuppressant as it inhibits the reproduction of rapidly dividing cells, especially lymphocytes.

Precautions and contraindications
- Contraindications:
  - Pregnancy – mothers require cholestyramine washout 3 months before conception or should cease ≥ 2 years before planned pregnancy.
  - Paternal exposure – based on very limited evidence, it may be safe but further studies to confirm this are warranted. Advise patients to discuss with their rheumatologist.
- Chronic liver disease.
- Significant haematological disorders.
- Stevens-Johnson syndrome.
- Severe infections or hypoproteinaemia or immunodeficiency.

- Warn patients about increased risk and severity of infections, and re-activation of latent infections e.g., hepatitis B or tuberculosis (TB).
- Live vaccines are not recommended.
- Very long half-life means interactions can occur many months after cessation.
- Many interactions including rifampicin, phenytoin, warfarin, tolbutamide, rosuvastatin, hepatotoxic, or haemotoxic medications. See Patient Information in prescribing software.

**Initiation and dose**
- Initiated under specialist advice.
- Maintenance 10 to 20 mg per day.
- Response may take 8 to 12 weeks.

**Side-effects**
- Common – diarrhoea (often moderate and may settle after 6 weeks – try alternate day doses), hypertension.
- Serious – more common with concurrent methotrexate. Includes severe infections, hepatic dysfunction, cytopaenias, rash, alopecia, interstitial lung disease and neuropathy.

**Monitoring**
- Use a reminder system.
- Ask about side-effects especially infections, cough or dyspnoea.
- FBE, LFT every 4 weeks, blood pressure monthly for first 3 months then every 3 months.
- Cease leflunomide (LFM) and seek [rheumatology advice](#) if:
  - neutropaenia or thrombocytopenia.
  - ALT > x 3 upper limit of normal.
  - pneumonitis (unexplained dyspnoea or cough).
  - peripheral neuropathy.

- Ideally baseline bloods including hepatitis serology will have been done before initiation.

### Methotrexate (MTX)

- Indications – rheumatoid arthritis and other rheumatic conditions e.g., juvenile arthritis, systemic lupus erythematosus, psoriasis, inflammatory bowel disease, polymyositis.
- First line for rheumatoid arthritis.
- Mode of action – folic acid antagonist.

**Precautions and contraindications**
- Contraindications:
  - Pregnancy – mothers should cease 3 months before planned pregnancy.
  - Alcohol abuse.
  - Hepatitis B and C or other chronic liver disease.
  - Interstitial lung disease.
  - Peptic ulceration.
• Advise patients MTX must be taken weekly. Agree on a specific day of the week and warn of potential for severe adverse effects if dose is exceeded.
• Give folic acid – either:
  o a weekly dose of 5 mg, on a different day to the MTX, e.g. 5 mg the day after the MTX is taken, or
  o a daily dose of 5 mg every day except the day the MTX is taken.

• Warn patients about increased risk and severity of infection and re-activation of latent infections e.g., hepatitis B or TB.
• Many interactions including trimethoprim and azathioprine. See Patient Information in prescribing software.
• Caution with live vaccines – seek rheumatology advice if any doubt.
• Vaccinate against hepatitis B prior to starting MTX

Initiation and dose
• Usually initiated under specialist advice.
• Maintenance 5 to 25 mg per week.
• Response usually takes 4 to 8 weeks.
• Dose may be split twice daily, given after food or given subcutaneous injection if nausea or poor efficacy.
• If mild renal impairment – lower dose required as renally excreted.

Side-effects
• Common – mouth ulcers, nausea (try parenteral or split doses and folate supplementation).
• Liver damage – more common with diabetes, obesity, alcohol, or concurrent leflunomide.
• Serious – cytopenias, pneumonitis, rash, alopecia.

Monitoring
• Use a reminder system.
• Ask about side-effects especially infections, cough or dyspnoea.
• FBE, E/LFT every 4 weeks for first 6 months then every 3 months.
• Cease MTX and seek rheumatology advice if:
  o neutropenia or thrombocytopenia.
  o ALT > x 3 upper limit of normal.
  o pneumonitis (unexplained dyspnoea or cough).

• Ideally chest X-ray and hepatitis serology if high risk will have been done as baseline.
• See NPS MedicineWise – Low-Dose Methotrexate factsheet.

Sulphasalazine (SSZ)

• Indications – rheumatoid arthritis, psoriatic arthritis and inflammatory bowel disease
• Mode of action – unknown (anti-inflammatory and immunosuppressant)

Precautions and contraindications
• Contraindications:
  o Previous reactions to sulphonamides.
  o Haematological, renal or hepatic dysfunction
• Cautions:
  o Pregnancy
    ▪ reversible effects on sperm motility.
    ▪ mothers require folic acid 5 mg daily but considered safe if benefits are greater than risks.
  o Severe infections.
  o G6PD deficiency.

• Warn patients about increased risk and severity of infections.
• Interactions include folic acid, digoxin, azathioprine, methotrexate, oral anticoagulants, and hypoglycaemics. See Patient Information in prescribing software.

**Initiation and dose**
• Usually initiated under specialist advice at 500 mg at night, increasing by 500 mg each week to maximum 1 gm twice a day.
• Maintenance 1 g twice daily.
• Response may take 6 to 16 weeks.

**Side-effects**
• Common – gastrointestinal effects (try reduced dose and re-titrate slowly).
• Serious – rare. Include severe infections, hepatic dysfunction, cytopaenias, haemolytic anaemia, rash, interstitial lung disease.

**Monitoring**
• Use a reminder system.
• Adverse events are usually within first 3 months.
• Ask about side-effects especially infections, rash, and gastrointestinal effects.
• FBE, E/LFT every 4 weeks for 3 months, then 2 to 3 monthly.
• Cease SSZ and seek **rheumatology advice** if:
  o haemolytic anaemia, neutropaenia, or thrombocytopenia.
  o alanine aminotransferase (ALT) > x 3 upper limit of normal.
  o severe rash (pruritus may indicate cholestatic hepatitis).
  o lung complications (unexplained dyspnoea or cough).

• Ideally baseline bloods will have been done before initiation.

**Biological DMARDS (bDMARDs)**

An expanding class of agents consisting of monoclonal antibodies or other agents which specifically target and interfere with a cytokine or an immunological cell involved in the inflammatory response.

In general, they are expensive, their properties overlap, and they require parenteral administration, but check Patient Information for detailed information about each individual agent. Can only be prescribed by specialist and require ongoing specialist reviews for applications to PBS.

• bDMARDS include:
  o Abatacept (ABA)
  o Adalimumab (ADA)
  o Anakinra (ANA)
  o Certolizumab (CTZ)
Etanercept (ETN)  
Golimumab (GOL)  
Infliximab (IFX)  
Rituximab (RTX)  
Secukinumab (SEC)  
Ixekizumab  
Tociluzimab (TCZ)  
Ustekinumab (USK)

- Indications – rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, inflammatory bowel disease, vasculitis and other immune mediated conditions.
- Mode of action – anti-inflammatory and immunosuppressant.

**Precautions and contraindications**

- **Contraindications:**
  - Previous hypersensitivity reactions to the agent.
  - Active infection.

- **Cautions:**
  - Pregnancy – some TNF medications are safe
  - Multiple sclerosis
  - Malignancy
  - Gastrointestinal perforation (tocilizumab)

- Risk of infection including re-activation of latent infection (e.g., hepatitis, TB).
- Avoid live vaccines – consider hepatitis B, flu, and pneumococcal vaccination.
- Increased risk of skin malignancy. Annual skin checks with a general practitioner or dermatologist are recommended.
- Risk of episodes of demyelination.
- Often used in conjunction with DMARDS, so continue monitoring for these.
- Warn patients about increased risk and severity of infections.
- Interactions – avoid live vaccines. Warfarin and other drugs metabolised by CYP450 (with TCZ). See Patient Information in prescribing software.

**Initiation and dose**

- Initiated under specialist management – see Patient Information for individual agent doses and timing.
- Response may take 2 to 6 months.

**Side-effects**

- Infusion and hypersensitivity reactions (if mild, these usually respond to antihistamine).
- Infections (including reactivation of latent infection), increased risk of skin malignancies, cytopaenias, hepatic and lipid abnormalities (TCZ), congestive cardiac failure (CCF), rashes.

**Monitoring**

- Monitoring is similar to that of DMARDS with variable initial frequency – and continues for any concurrent DMARDS.
- Some rheumatologists recommend FBE, E/LFT every 3 months especially for TCZ.
- Ask about side-effects especially infections.
- Seek [rheumatology advice](#) and consider ceasing bDMARD if:
- Significant infection or TB.
- Drug-induced lupus (rash, arthralgia, and glomerulonephritis).
- Malignancy.
- Cytopaenia.
- Cardiac failure.
- Neurological event.
- Severe hypersensitivity reaction.
- Hepatic dysfunction (tocilizumab).

**JAK Inhibitors**

- JAK Inhibitors are:
  - A new class of synthetic drugs that are selective inhibitors of Janus kinase (JAK) enzymes.
  - Associated with cytokine receptors on the surface of cells.
  - Part of the Signal Transducer and Activation of Transcription (JAK-STAT) pathway which is involved in inflammatory and immune responses.
  - Oral tablet medications, but their mechanism of action and side-effects have more in common with biologic agents.

- In general, expensive, and their properties overlap.
- JAK Inhibitors include:
  - Tofacitinib
  - Ruxolitinib
  - Baricitinib
  - Upadacitinib

- Indications – rheumatoid arthritis, psoriatic arthritis, myelofibrosis, polycythaemia vera.
- Mode of action – anti-inflammatory and immunosuppressant.
- Can only be prescribed by specialist and require ongoing specialist reviews for applications to PBS.

**Precautions and contraindications**

- Contraindications:
  - Previous hypersensitivity reactions to the agent.
  - Concurrent treatment with biological DMARDS, azathiopeprine, or cyclosporin.
  - Severe hepatic impairment.

- Cautions:
  - Pregnancy
  - Malignancy
  - Prior thromboembolic disease – contraindicated in those with unprovoked DVT/PE history or known thrombophilia. Use with great caution in those at risk of thromboembolic disease.
  - Gastrointestinal perforation
  - Renal transplant

- Risk of infection including re-activation of latent infection (e.g., herpes zoster, hepatitis, TB).
- Avoid live vaccines (including Varicella-Zoster).
- Consider hepatitis B, influenza (yearly), and pneumococcal vaccination.
- Small increase risk of thromboembolic disease.
• Risk of development of skin malignancy (melanoma).
• Warn patients about increased risk and severity of infections.
• Interactions – warfarin and other drugs metabolised by CYP450 (with TCZ). See Patient Information in prescribing software.

Initiation and dose
• Initiated under specialist management – see Patient Information for individual agent doses and timing.
• Response may take up to 6 months.

Side-effects
• Infections (including reactivation of latent infection), malignancies, cytopaenias, hepatic and lipid abnormalities, hypertension, insomnia, headaches, rashes.

Monitoring
• No specific tests but monitoring continues for any concurrent DMARDs.
• Some rheumatologists recommend FBE, E/LFT, cholesterol every 3 months.
• Ask about side-effects especially infections.
• Seek rheumatology advice and consider ceasing DMARD if:
  o significant infection or TB.
  o drug induced lupus (rash, arthralgia, and glomerulonephritis).
  o malignancy.
  o cytopaenia.
  o cardiac failure.
  o neurological event.
  o severe hypersensitivity reaction.
  o severe hepatic dysfunction.

Information

For health professionals

Further information
• Australian Prescriber – Managing the Drug Treatment of Rheumatoid Arthritis
• Australian Rheumatology Association:
  o GPs
  o Position Statements and other Clinical Recommendations
• Patient – Disease-modifying Antirheumatic Drugs (DMARDs)

For patients

Australian Rheumatology Association – Medication Information
References


Disclaimer

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