Applicant: Teva Pharmaceuticals (Pty) Ltd	**Product name:** Azathioprine 50 PCH **Dosage form & strength:** Each tablet contains 50 mg Azathioprine **Module 1.3.2.1:** PIL – Approved eCTD 0007 **Date of submission:** 10 July 2026

APPROVED PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: S4

AZATHIOPRINE 50 PCH (Tablets)

Each tablet contains 50 mg azathioprine.

Contains sugar: 60 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking AZATHIOPRINE 50 PCH:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse, or other health care provider.
- AZATHIOPRINE 50 PCH has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT IS IN THIS LEAFLET:

1. WHAT AZATHIOPRINE 50 PCH IS AND WHAT IT IS USED FOR:

AZATHIOPRINE 50 PCH contains the active substance azathioprine.

AZATHIOPRINE 50 PCH belongs to a group of medicines known as immunosuppressants.

AZATHIOPRINE 50 PCH is used to reduce the body's natural immunity in patients who receive organ transplants.

AZATHIOPRINE 50 PCH may be used on its own, but it is more often used in combination with other medicines.

AZATHIOPRINE 50 PCH is also used to treat rheumatoid arthritis (inflammation and pain in your joints).

AZATHIOPRINE 50 PCH may be used for other autoimmune diseases such as chronically active and aggressive hepatitis (inflamed liver), systemic lupus erythematosus (a disease which affects your skin and major organs) and pemphigus vulgaris (skin disease).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AZATHIOPRINE 50 PCH:

Do not take AZATHIOPRINE 50 PCH:

- If you are hypersensitive (allergic) to azathioprine, 6-mercaptopurine or any of the other ingredients of AZATHIOPRINE 50 PCH (listed in **section 6**).
- If you have a severe infection or problems with your bone marrow.
- If you have severe liver impairment.
- If you have problems with your pancreas (known as pancreatitis).
- If you have received a live vaccine (particularly tuberculosis (BCG), smallpox and yellow fever vaccines).
- If you are pregnant.
- If you are breastfeeding your baby, see **Pregnancy, breastfeeding and fertility**.

Warnings and precautions:

Take special care with AZATHIOPRINE 50 PCH:

Inform your doctor before taking AZATHIOPRINE 50 PCH:

- if you have kidney or liver problems. You may have to take a lower dose and your doctor will closely monitor you
- if you experience any evidence of infection (e.g. fever, sore throat), unexpected bruising and/or bleeding
- if you are planning to become pregnant
- if you experience loss of appetite, nausea, vomiting or diarrhoea
- if you ever have or have had any problems with your digestive system e.g. inflammatory bowel disease

- if you are taking continuous AZATHIOPRINE 50 PCH together with corticosteroids you may have a persistent negative nitrogen balance. This means that the amount of nitrogen excreted from the body is greater than the amount of nitrogen ingested
- if you have ever had chicken pox or shingles, and you should also avoid contact with anyone who has these viruses
- if you have hepatitis B (a liver disease caused by a virus)
- if you have an inherited mutated NUDT15 gene (a gene which is involved in the break-down of AZATHIOPRINE 50 PCH in the body). You have a higher risk of infections and hair loss and your doctor may in this case give you a lower dose
- if you have a genetic condition called TPMT deficiency (where your body produces too little of an enzyme called 'thiopurine methyltransferase')
- you have a rare hereditary deficiency of hypoxanthine-guanine phosphoribosyl-transferase (HGPRT) known as Lesch-Nyhan syndrome
- you are taking other medicines such as allopurinol used to treat gout (which is a painful swelling of the foot due to excess acid), or anticoagulant medicines (used to prevent blood clots) (see "Other medicines with AZATHIOPRINE 50 PCH")
- if you have recently received, or are due to receive a vaccination (vaccine) (see **"Other medicines with AZATHIOPRINE 50 PCH"**)
- if you are taking an antiviral medicine called ribavirin
- if you are going to have an operation or are currently taking neuromuscular blocking medicines such as atracurium, rocuronium, cisatracurium, tubocurarine or suxamethonium (also known as succinylcholine) (see **"Other medicines with AZATHIOPRINE 50 PCH"**)

Liver damage:

Treatment with AZATHIOPRINE 50 PCH may affect the liver and your doctor will monitor your liver function regularly. Tell your doctor if you experience symptoms of liver damage (see **section 4 "Possible side effects"**).

If you are receiving immunosuppressive therapy, AZATHIOPRINE 50 PCH could put you at greater risk of:

- Tumours, including skin cancer. Therefore, when taking AZATHIOPRINE 50 PCH, avoid excessive exposure to sunlight and UV light, wear protective clothing and use protective sunscreen with a high protection factor.
- Lymphoproliferative disorders:
- Treatment with AZATHIOPRINE 50 PCH increases your risk of getting a type of cancer called lymphoproliferative disorder. With treatment regimen containing multiple immunosuppressants (including thiopurines), this may lead to death.
- A combination of multiple immunosuppressants, given concomitantly increases the risk of disorders of the lymph system due to a viral infection (Epstein-Barr virus (EBV)-associated lymphoproliferative disorders).

Taking AZATHIOPRINE 50 PCH could put you at greater risk of:

- Developing a serious condition called Macrophage Activation Syndrome (excessive activation of white blood cells associated with inflammation), which usually occurs in people who have certain types of arthritis.
- Severe chickenpox or shingles infection. Therefore, when taking AZATHIOPRINE 50 PCH, avoid contact with people who have chickenpox or shingles.
- A previous hepatitis B infection becoming active again.
- Other infections such as PML (Progressive Multifocal Leukoencephalopathy) which is an opportunistic infection.

If you experience any signs of infection, please contact your doctor (see **section 4 "Possible side effects"**).

Your doctor will need to monitor you closely throughout your treatment. You should therefore visit your doctor regularly whilst taking AZATHIOPRINE 50 PCH so your condition can be checked.
You will need to have your blood count checked at least once a week for the first two months of treatment and then monthly.

AZATHIOPRINE 50 PCH may cause you to experience abnormally coloured urine, such as bright yellow urine. Although bright yellow urine is generally not concerning, you should discuss any change in the colour of your urine – including other discolorations or darkening – with your doctor, as this may indicate kidney or liver problems.

Talk to your doctor immediately if you experience diarrhoea, localized pigmented rash (dermatitis), decline in your memory, reasoning or other thinking skills (dementia) as these symptoms may suggest vitamin B3 deficiency (nicotinic acid deficiency/pellagra).

Other medicines with AZATHIOPRINE 50 PCH:

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor if you are taking, have recently taken or might take any other medicines. This is because AZATHIOPRINE 50 PCH can affect the way some medicines work. Also some other medicines can affect the way AZATHIOPRINE 50 PCH works.

In particular tell your doctor if you are taking, or are planning to take:

- allopurinol, oxipurinol, thiopurinol or other xanthine oxidase inhibitors, such as febuxostat (used to treat gout or kidney stones)
- neuromuscular blocking medicines such as tubocurarine, curare, pancuronium or succinylcholine (medicines used during operations to relax muscles) (see **section 2 "Warnings and precautions"**)
- any other medicines such as ciclosporin, or tacrolimus used to suppress your immune system
- penicillamine (used for rheumatoid arthritis)
- cimetidine (used for stomach ulcers and indigestion)
- indomethacin (used for pain and inflammation)
- furosemide (used for high blood pressure and heart problems)
- trimethoprim/ sulfamethoxazole (co-trimoxazole) (an antibiotic used to treat infections)
- ACE inhibitors such as captopril (used to treat high blood pressure)

- olsalazine, mesalazine, or sulfasalazine (mainly used to treat ulcerative colitis and Crohn's disease)
- anticoagulant medicines such as warfarin or acenocoumarol (used to 'thin' the blood and prevent blood clots)
- infliximab (used to treat auto immune diseases)
- ribavirin (used to treat certain viral infections such as hepatitis C)
- methotrexate (used to treat certain cancers, auto immune diseases, rheumatoid arthritis and a skin condition known as psoriasis).
- cytostatic medicines (medicines used to treat various types of cancer)

Before a surgical procedure tell the anaesthesiologist that you are taking AZATHIOPRINE 50 PCH because muscle relaxants used during anaesthesia may interact with AZATHIOPRINE 50 PCH.

If you have recently received, or are due to receive, a vaccination/ immunisation (vaccine). If you take AZATHIOPRINE 50 PCH, you should not have a live organism vaccine (for example; flu vaccine, measles vaccine, BCG vaccine, etc.) until advised it is safe to do so by your doctor. This is because some vaccines may give you an infection if you receive them while you are taking AZATHIOPRINE 50 PCH.

AZATHIOPRINE 50 PCH with food and drink:

AZATHIOPRINE 50 PCH sometimes causes nausea (feeling sick) or vomiting.

Taking AZATHIOPRINE 50 PCH after meals or at bedtime may lessen an upset stomach.

AZATHIOPRINE 50 PCH should not be taken with milk or dairy products.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking AZATHIOPRINE 50 PCH.

Pregnancy:

The safety of AZATHIOPRINE 50 PCH in pregnancy has not been established.

Do not take AZATHIOPRINE 50 PCH if you are pregnant, become pregnant, or suspect you may already be pregnant as AZATHIOPRINE 50 PCH could harm your baby.

Women of childbearing potential and men receiving AZATHIOPRINE 50 PCH should use effective contraception during and for at least three months for men and six months for women after the end of AZATHIOPRINE 50 PCH therapy.

Talk to your doctor immediately if you experience intense itching without a rash during your pregnancy. You may also experience nausea, and loss of appetite together with itching, which indicates that you have a condition called cholestasis of pregnancy (condition affecting the liver during pregnancy).

Breastfeeding:

The safety of AZATHIOPRINE 50 PCH in breastfeeding has not been established.

Small amounts of AZATHIOPRINE 50 PCH may pass into the breast milk. It is recommended that women taking AZATHIOPRINE 50 PCH should avoid breastfeeding.

Fertility:

The effects of AZATHIOPRINE 50 PCH on fertility are not known.

Driving and using machines:

AZATHIOPRINE 50 PCH has a moderate influence on the ability to drive and use machines.

It is not always possible to predict to what extent AZATHIOPRINE 50 PCH may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which AZATHIOPRINE 50 PCH affects you (see **section 4 "Possible side effects"**).

AZATHIOPRINE 50 PCH contains lactose monohydrate:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking AZATHIOPRINE 50 PCH.

3. HOW TO TAKE AZATHIOPRINE 50 PCH:

Do not share medicines prescribed for you with any other person.

Always take AZATHIOPRINE 50 PCH exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your dose will be adjusted depending on your weight and according to your condition.

The recommended doses are:

To prevent organ rejection:

The recommended starting dose is up to 5 mg per kg of body weight per day. Your doctor will then assess your response to AZATHIOPRINE 50 PCH and choose the best dose for you. This may take weeks or months. After this assessment your dose will usually be between 1 mg and 4 mg per kg of body weight per day.

Other conditions:

The recommended starting dose is between 1 mg and 2,5 mg per kg of body weight per day. Your doctor will adjust the dose until it is right for you. Your doctor will prescribe the lowest dose that is effective to treat your condition.

If there is no improvement within three months, your doctor may stop giving you AZATHIOPRINE 50 PCH.

Older people or people with kidney or liver disease:

If you are elderly or you have kidney or liver disease, you may be started on a lower dose of AZATHIOPRINE 50 PCH .Your doctor will monitor your blood and liver function carefully. Your dose may be reduced further if there are any signs that your blood or liver is affected.

Method of administration:

AZATHIOPRINE 50 PCH tablets should be taken by mouth.

AZATHIOPRINE 50 PCH tablets may be taken with food or on an empty stomach.

If you feel sick after taking your AZATHIOPRINE 50 PCH tablets, it should help to take your tablets after meals.

AZATHIOPRINE 50 PCH tablets should not be taken with milk or dairy products (see **section 2 "AZATHIOPRINE 50 PCH with food and drink"**).

It is important that carers are aware of the need for safe handling of AZATHIOPRINE 50 PCH. If you or your caregiver handle broken tablets, wash your hands immediately. Please consult your doctor or pharmacist for advice.

Your doctor will tell you how long your treatment with AZATHIOPRINE 50 PCH will last. Do not stop taking this medicine without first checking with your doctor. If you have the impression that the effect of AZATHIOPRINE 50 PCH is too strong or too weak, tell your doctor or pharmacist.

If you take more AZATHIOPRINE 50 PCH than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose include nausea (feeling sick), vomiting (being sick) and diarrhoea, lack of white blood cells which may cause frequent infections such as fever, severe chills, sore throat or mouth ulcers, disturbances of your liver function, bruising and bleeding.

If you forget to take AZATHIOPRINE 50 PCH:

If you forget to take a dose of AZATHIOPRINE 50 PCH, take it as soon as you remember, then carry on with the next dose at the usual time. Do not take a double dose to make up for forgotten individual doses.

If you stop using AZATHIOPRINE 50 PCH:

Discontinuation of AZATHIOPRINE 50 PCH therapy, even after a period of years, carries a risk of transplant rejection within a few weeks.

After you stop using AZATHIOPRINE 50 PCH, it may still produce some side effects that need attention.

During this period of time, check with your doctor as soon as possible if you notice any of the following:
Black, tarry stools; blood in urine; cough or hoarseness; fever or chills; lower back or side pain; painful or difficult urination; pinpoint red spots on skin; unusual bleeding or bruising.

Do not stop taking AZATHIOPRINE 50 PCH because you feel better. It is important to take AZATHIOPRINE 50 PCH for as long as the doctor has told you to. Do not stop taking AZATHIOPRINE 50 PCH unless your doctor tells you to.

If you have any further questions on the use of AZATHIOPRINE 50 PCH, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS:

AZATHIOPRINE 50 PCH can have side effects.
Not all side effects reported for AZATHIOPRINE 50 PCH are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while taking AZATHIOPRINE 50 PCH, please consult your health care provider for advice.

If any of the following happens, stop taking AZATHIOPRINE 50 PCH and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- redness of the skin, skin nodules or a skin rash, high temperature (fever), shivering or chills, headache, general tiredness, dizziness, feeling sick (nausea), being sick (vomiting) or diarrhoea, pain in the muscles or joints, dizziness, confusion, feeling light headed or weak (caused by low blood pressure)
- skin rashes or redness, which may develop into life-threatening skin reactions including widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), extensive peeling of the skin (toxic epidermal necrolysis, TEN).

These are all very serious side effects. If you have them, you may have had a serious reaction to AZATHIOPRINE 50 PCH. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- if you have a high temperature (fever) or other signs of an infection such as sore throat, sore mouth, urinary problems, or chest infection causing breathlessness and cough
- problems with your blood and bone marrow which may cause unexpected bruising or bleeding, weakness, breathlessness, tiredness, paleness, dizziness or an infection
- various types of tumours or cancers including blood, lymph and skin cancers (see **section 2 "Warnings and precautions"**)
- reversible pneumonitis (inflammation of your lungs causing cough, shortness of breath and fever)
- inflammation of the pancreas (characterised by upper abdominal pain, nausea and vomiting)
- liver disease or liver injury (characterised by yellowing of eyes and skin, abdominal pain, dark urine, pale colour stool and fatigue) (jaundice)
- when AZATHIOPRINE 50 PCH are used in combination with other immunosuppressives you may get a virus which causes damage to your brain. This may cause headaches, changes in behaviour, impaired speech, worsening of abilities such as memory, attention and decision making (cognitive decline) and may be fatal (condition known as JC virus associated Progressive Multifocal Leukoencephalopathy)
- rash (raised red, pink or purple lumps which are sore to touch), particularly on your arms, hands, fingers, face and neck, which may also be accompanied by a fever (high temperature) (Sweet's syndrome, also known as 'acute febrile neutrophilic dermatosis')
- a certain type of lymphomas (hepatosplenic T-cell lymphoma). You may develop nose bleeds, fatigue, significant night sweats, weight loss and unexplained fevers (high temperature)
- kidney failure with symptoms such as swelling of your ankles, painful urination, producing less urine than what is normal for you and blood in your urine

- changes in the way your heart beats, for example, if you notice it beating faster
- symptoms indicating reversible swelling of the brain with symptoms including severe headache, vision changes, seizures, confusion and reduced consciousness, with or without high blood pressure (Posterior Reversible Encephalopathy Syndrome or PRES).

These are all serious side effects. You may need urgent medical attention.

Frequent side effects:

- nausea (feeling sick) and being sick (vomiting).

Less frequent side effects:

- stomach pain, mouth ulcers or sores, inflammation of the stomach or the food pipe (oesophagus), heartburn, stomach ulcers, changes in stool colour (such as bloody or pale stools)
- bleeding in the digestive tract, which may appear as blood in your stool or vomit — this could be due to serious internal bleeding or a hole (perforation) in the bowel
- problems with intestines or bowel problems that may cause severe diarrhoea, stomach pain, constipation, feeling sick (nausea) or being sick (vomiting) — possibly due to bowel damage such as a tear (perforation)
- cholestasis of pregnancy, which can cause intense itching, especially on the hands and feet
- skin sensitivity to sunlight
- hair loss.

Side effects with an unknown frequency:

- blurred or abnormal vision (damage to the retina of the eyes which may cause vision impairment)
- fingers and toes feel numb and cold in response to cold temperatures (Raynaud's phenomenon)
- changes in the colour of the skin and nails
- muscle and joint pain
- suppression of normal function of the ovaries and testicles causing the absence of periods (menstruation) and the inhibition of formation of sperm

- inflammation of the mouth, which may include redness, swelling, pain, or sores (ulcers) on the lips, tongue, inner cheeks, or gums (stomatitis)
- abnormalities in chromosomes (e.g. Down syndrome)
- tiredness, fever, shivers, weakness
- abnormal levels of phosphate or nitrogen in the blood
- loss of appetite (anorexia)
- pellagra (lack of vitamin B3 (niacin) associated with pigmented rash, diarrhoea, or loss of memory
- severe liver damage which can be life threatening, especially in patients who receive long-term treatment (like liver injury, non-cirrhotic portal hypertension, portosinusoidal vascular disease). Tell your doctor if you experience any of the following symptoms: yellowing of the skin and the whites of the eyes (jaundice), bruising easily, abdominal discomfort, loss of appetite, fatigue, nausea, or vomiting
- headache, dizziness
- low blood pressure
- abnormal levels of uric acid in the blood, difficulty or decreased urination or gout (painful swelling of the foot due to excess acid)
- abnormally coloured urine, such as bright yellow urine (chromaturia)
- tremor
- inflammation or infection of the salivary glands

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of AZATHIOPRINE 50 PCH.

5. HOW TO STORE AZATHIOPRINE 50 PCH:

Store at or below 25 °C and protect from light.

Keep blisters in outer carton until required for use.

Store all medicines out of reach of children.

Do not take AZATHIOPRINE 50 PCH after the expiry date shown on the pack.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What AZATHIOPRINE 50 PCH contains:

The active substance is 50 mg of azathioprine.

The other ingredients are colloidal anhydrous silica, lactose monohydrate, magnesium stearate, potato starch, povidone.

What AZATHIOPRINE 50 PCH looks like and contents of the pack:

AZATHIOPRINE 50 PCH:

Yellow, biconvex tablets with score line and embossed description: AZP | 50 on one side and without marking and the score line on the other.

Contents of pack:

Aluminium/PVC/PVDC and transparent green PVC foil blister strips. 10 Tablets per blister and 10 blister strips per outer carton.

White HDPE containers with white PP closure with space filler (polyurethane). Pack sizes of 90, 100, 150 or 250 tablets.

HOLDER OF THE CERTIFICATE OF REGISTRATION:

Teva Pharmaceuticals (Pty) Ltd,

Maxwell Office Park,

Magwa Crescent West,

Waterfall City,

Midrand,

Gauteng,

2090.

Tel: (011) 055 0200

This leaflet was last revised in:

19 June 2026

REGISTRATION NUMBER:

37/26/0692

Access to the corresponding Professional Information:

Website: https://www.teva.co.za/

The Professional Information can also be obtained from:

Teva Pharmaceuticals (Pty) Ltd,

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Waterfall City,

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Namibia

Reg. No.: 13/26/0126

NS2

Botswana:

10 x 10's PVC/Alu blister Reg. No.: BOT1803358

S2