Azathioprine may increase your risk of developing certain types of cancer, especially skin cancer and lymphoma (cancer that begins in the cells that fight infection). If you have had a kidney transplant, there may be a higher risk that you will develop cancer even if you do not take azathioprine. Tell your doctor if you have or have ever had cancer and if you are taking or have ever taken alkylating agents such as chlorambucil (Leukeran), cyclophosphamide (Cytoxan), or melphalan (Alkeran) for cancer. To decrease the risk that you will develop skin cancer, avoid prolonged or unnecessary exposure to sunlight and wear protective clothing, sunglasses, and sunscreen. Tell your doctor immediately if you notice any changes in your skin or any lumps or masses anywhere in your body.

Some teenage and young adult males who took azathioprine alone or with another medication called a tumor necrosis factor (TNF) blocker to treat Crohn's disease (a condition in which the body attacks the lining of the digestive tract causing pain, diarrhea, weight loss, and fever) or ulcerative colitis (a condition which causes swelling and sores in the lining of the colon [large intestine] and rectum) developed hepatosplenic T-cell lymphoma (HSTCL). HSTCL is a very serious type of cancer that often causes death within a short period of time. Azathioprine has not been approved by the Food and Drug Administration (FDA) for the treatment of Crohn's disease or ulcerative colitis, but doctors may sometimes prescribe azathioprine to treat these conditions. If you develop any of these symptoms during your treatment, call your doctor immediately: stomach pain; fever; unexplained weight loss; night sweats or easy bruising or bleeding.

Azathioprine can cause a decrease in the number of blood cells in your bone marrow, which may cause serious or life-threatening infections. The risk that the number of blood cells that you have will decrease is highest if you have a genetic (inherited) risk factor. Your doctor may order a test to see if you have this risk factor before or during your treatment. Taking certain medications may also increase the risk that your blood cells will decrease, so tell your doctor if you are taking any of the following: angiotensin converting enzyme (ACE) inhibitors such as benazepril (Lotensin), captopril,
enalapril (Vasotec), fosinopril, lisinopril (Prinivil, Zestril), moexipril (Univasc), perindopril (Aceon), quinapril (Accupril), Ramipril (Altace), or trandolapril (Mavik); trimethoprim and sulfamethoxazole (Bactrim, Septra); and ribavirin (Copegus, Rebetol, Virazole). If you experience any of the following symptoms, call your doctor immediately: unusual bleeding or bruising; excessive tiredness; pale skin; headache; confusion; dizziness; fast heartbeat; difficulty sleeping; weakness; shortness of breath; and sore throat, fever, chills, and other signs of infection. Your doctor will order tests before, during, and after your treatment to see if your blood cells are affected by this medication.

Talk to your doctor about the risks of taking this medication.

**Why is this medication prescribed?**

Azathioprine is used with other medications to prevent transplant rejection (attack of the transplanted organ by the immune system) in people who received kidney transplants. It is also used to treat severe rheumatoid arthritis (a condition in which the body attacks its own joints, causing pain, swelling, and loss of function) when other medications and treatments have not helped. Azathioprine is in a class of medications called immunosuppressants. It works by decreasing the activity of the body's immune system so it will not attack the transplanted organ or the joints.

**How should this medicine be used?**

Azathioprine comes as a tablet to take by mouth. It is usually taken once or twice a day after meals. Take azathioprine at around the same time(s) every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take azathioprine exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

If you are taking azathioprine to treat rheumatoid arthritis, your doctor may start you on a low dose and gradually increase your dose after 6-8 weeks and then not more than once every 4 weeks. Your doctor may gradually decrease your dose when your condition is controlled. If you are taking azathioprine to prevent kidney transplant rejection, your doctor may start you on a high dose and decrease your dose gradually as your body adjusts to the transplant.

Azathioprine controls rheumatoid arthritis but does not cure it. It may take up to 12 weeks before you feel the full benefit of azathioprine. Azathioprine prevents transplant rejection only as long as you are taking the medication. Continue to take azathioprine even if you feel well. Do not stop taking azathioprine without talking to your doctor.

**Other uses for this medicine**

Azathioprine is also used to treat ulcerative colitis (a condition which causes swelling and sores in the
lining of the colon [large intestine] and rectum) and Crohn's disease. Talk to your doctor about the possible risks of using this medication for your condition.

This medication is sometimes prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking azathioprine,

- tell your doctor and pharmacist if you are allergic to azathioprine, any other medications, or any of the ingredients in azathioprine tablets. Ask your doctor or pharmacist for a list of the ingredients.

- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medications mentioned in the IMPORTANT WARNING section and any of the following: allopurinol (Zyloprim); aminosalicylates such as mesalamine (Apriso, Asacol, Pentasa, others), olsalazine (Dipentum), and sulfasalazine (Azulfidine); and anticoagulants ('blood thinners') such as warfarin (Coumadin). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor if you have any type of infection, or if you have or have ever had kidney disease.

- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. You should use birth control to be sure you or your partner will not become pregnant while you are taking this medication. Call your doctor if you or your partner become pregnant while you are taking azathioprine. Azathioprine may harm the fetus.

- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking azathioprine.

- do not have any vaccinations during or after your treatment without talking to your doctor.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Azathioprine may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
Some side effects can be serious. If you experience any of the following symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately.

- rash
- fever
- weakness
- muscle pain

This medication may cause other side effects. Call your doctor if you have any unusual problems while you are taking azathioprine.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at http://www.fda.gov/Safety/MedWatch] or by phone [1-800-332-1088].

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Symptoms of overdose may include the following:

- nausea
- vomiting
- diarrhea
- sore throat, fever, chills, and other signs of infection

What other information should I know?

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.
It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

**Brand names**

- Azasan ®
- Imuran ®

Last Revised - 05/15/2014