Package leaflet: Information for the patient

Azathioprine AqVida 50 mg film-coated tablets

Azathioprine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Azathioprine AqVida is and what it is used for

Azathioprine AqVida contains the active ingredient azathioprine, which belongs to a group of medicines called immunosuppressives. Immunosuppressives reduce the strength of your immune system.

Your doctor has prescribed Azathioprine AqVida tablets for one of the following conditions:
- To help your body accept an organ transplant.
- To control some diseases where your immune system is reacting against your own body.

Azathioprine AqVida can also be used alone or in combination with other medicines to treat severe rheumatoid arthritis, severe inflammation of the gut (Crohn's disease or ulcerative colitis), or to treat some diseases where your immune system is reacting against your own body (auto-immune disease) including severe inflammatory diseases of the skin, liver, artery and some blood disorders.

2. What you need to know before you take Azathioprine AqVida

Do not take Azathioprine AqVida:
- if you are allergic to azathioprine, mercaptopurine or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, difficulty of breathing or swelling of the face, lips, throat or tongue.
- if you have severe infections.
- if you have severe liver or bone marrow disorder.
- if you have pancreatitis (inflammation of the pancreas).
- if you have recently had a vaccinations with live vaccine such as smallpox or yellow fever.
- if you are pregnant (unless your doctor tells you).
- if you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Azathioprine AqVida.

You will not be given Azathioprine AqVida unless you can be monitored for side effects.

You should tell your doctor straight away if you develop ulcers of the throat, fever, infections, bruising, or bleeding.

Talk to your doctor before taking Azathioprine AqVida, if you are going to have a vaccination while you are taking Azathioprine AqVida.
- if you have a condition where your body produces too little of a natural chemical called thiopurine methyltransferase (TPMT).
- if you suffer from a condition known as Lesch-Nyhan Syndrome.

If you are receiving immunosuppressive therapy, taking Azathioprine AqVida could put you at greater risk of:
- tumours, including skin cancer. Therefore, when taking Azathioprine AqVida, avoid excessive exposure to sunlight, wear protective clothing and use protective sunscreen with a high protection factor.
- lymphoproliferative disorders
    - treatment with Azathioprine AqVida 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 AqVida 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.

The tablet can be divided into the equal doses. If the tablet has to be halved, contact of the skin with tablet dust or the broken area must be avoided. Do not crush the tablets.

Blood tests
You will need a blood test once a week during the first 8 weeks of treatment. You may need blood tests more often if you:
- are elderly.
- are taking a high dose.
- have a liver or kidney disorder.
- have a bone marrow disorder.
- have an overactive spleen.

It is important that you use effective contraception (such as condoms) as Azathioprine AqVida may cause birth defects when taken by either the man or woman.

Warning
Any withdrawal of Azathioprine AqVida should be performed under close monitoring. Please ask your doctor.

Other medicines and Azathioprine AqVida
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, e.g.:
- Allopurinol, oxipurinol or thiopurinol (treatments for gout),

- Muscle relaxants such as curare, d-tubocurarine, pancuronium, or succinylcholine,
- Other immunosuppressants such as cyclosporin or tacrolimus,
- Infliximab (a treatment for Crohn's disease),
- Olsalazine, mesalazine and sulfasalazine (treatment for ulcerative colitis),
- Warfarin or phenprocoumon (blood thinners),
- ACE-inhibitors (treatments for high blood pressure or heart failure),
- Trimethoprim and sulfamethoxazole (antibiotics),
- Cimetidine (treatment for ulcers of the digestive tract),
- Cancer treatments or treatments that slow or stop the production of new blood cells,
- Furosemide (a water tablet for heart failure),
- Vaccines such as hepatitis B,
- Any "live" vaccine.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

You must not take Azathioprine AqVida if you are pregnant unless your doctor tells you to.
Both male and female patients of reproductive age should use a contraceptive other than an interuterine device (e.g. coil, Copper T). You should continue to use a contraceptive for three months after treatment with Azathioprine AqVida has stopped.
You must not breast-feed during treatment with Azathioprine AqVida, as metabolic products produced in the body pass into the breast milk and can damage your child.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
You are safe to drive or operate machinery when taking Azathioprine AqVida unless you experience dizziness. Dizziness maybe made worse by alcohol and you should not drive or operate machinery if you have been drinking alcohol.

Azathioprine AqVida contains lactose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Azathioprine AqVida

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The tablets should be taken during meals with a glass of liquid.

Dosage

Patients who have had a transplant
The usual first day dose is up to 5 mg/kg of body weight per day. The usual dose is then 1 – 4 mg/kg of body weight per day.

Other disorders
The usual dosage is 1 - 3 mg/kg of body weight per day.

Use in children and adolescents

Azathioprine AqVida are not recommended for the use in children below18 years due to insufficient data for the treatment of juvenile chronic arthritis, systemic lupus erythematosus, dermatomyositis and polyarteritis nodosa.
For all other indications, the given dose recommendations apply for children and adolescents as well as for adults.

Elderly
The elderly may need a reduced dose.

Patients with a liver or kidney disorder
Patients with a liver or kidney disorder may need a reduced dose. Patients with severe liver disorder must not take Azathioprine AqVida.

The duration of treatment with Azathioprine AqVida is determined by your doctor. Please ask your doctor if you think that the effect of Azathioprine AqVida is too strong or too weak.

If you take more Azathioprine AqVida than you should
Contact your doctor, pharmacist or nearest hospital immediately.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

Serious side effects
If you develop any of the following side effects, contact your doctor immediately:
- Severe sickness,
- Diarrhoea,
- Fever, chills,
- Muscle or bone pain, muscle stiffness,
- Tiredness, dizziness,
- Inflammation of the blood vessels,
- Kidney disorders (symptoms may include changes in the amount of urine passed and changes in its colour).

The following side effects have also been reported:

Very common (may affect more than 1 in 10 people):
- infections caused by a virus, fungus or bacteria in transplant patients,
- reduction in your bone marrow function,
- low white blood cell level in your blood tests, which may cause an infection,
- feeling sick (nausea) and being sick (vomiting), loss of appetite (anorexia).

Common (may affect up to 1 in 10 people):
- low blood platelet level, which may cause you to bruise or bleed easily.

Uncommon (may affect up to 1 in 100 people):
- infections caused by a virus, fungus or bacteria in all patients except transplant patients,

- low red blood cell level, which may cause you to be tired, get headaches, be short of breath when exercising, feel dizzy and look pale,
- hypersensitivity reactions, which may lead to general discomfort, dizziness, feeling sick, vomiting, diarrhoea, fever, shivering, skin reactions like exanthema and rash, inflammation of the blood vessels, muscle and joint pain, low blood pressure, kidney or liver disorders and problems with your bowel,
- inflammation of the pancreas, which may cause you severe upper stomach pain, with feeling sick (nausea) and being sick (vomiting),
- liver problems, which may cause pale stools, dark urine, itchiness and yellowing of your skin and eyes, and abnormalities in the results of liver function tests.

Rare (may affect up to 1 in 1,000 people):
- problems with your blood and bone marrow which may cause weakness, tiredness, paleness, headaches, sore tongue, breathlessness, bruising or infections,
- problems with your bowel leading to diarrhoea, abdominal pain, constipation, feeling sick (nausea) and being sick (vomiting),
- severe liver damage which can be life threatening,
- hair loss which may get better even though you continue to take Azathioprine AqVida,
- various types of cancers including blood, lymph and skin cancers.

Very rare (may affect up to 1 in 10,000 people):
- life-threatening allergic reactions leading to severe conditions affecting the skin (Stevens-Johnson syndrome and toxic epidermal necrolysis),
- inflammation of your lungs causing breathlessness, cough and a fever.
- cases of PML, an infection of the central nervous system caused by the JC virus have been reported after using azathioprine in combination with other immunosuppressants.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [to be completed nationally]}. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Azathioprine AqVida

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the blister and the carton after ''EXP''. The expiry date refers to the last day of that month.

Keep the blister in the original package in order to protect from light.

Do not use this medicine if you notice any visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Azathioprine AqVida contains

- The active substance is azathioprine.
- 1 film-coated tablet contains 50 mg azathioprine.

- The other ingredients are:

Core tablet: lactose monohydrate, microcrystalline cellulose, sodium starch glycollate (Type A) (Ph.Eur.), pregelatinised starch (maize), polysorbate 80, povidone K30, magnesium stearate (Ph.Eur.) [plant]

Film coating: hypromellose, macrogol 400, macrogol 6000

What Azathioprine AqVida looks like and contents of the pack

Azathioprine AqVida 50 mg film-coated tablets are pale yellow coloured, film-coated, round, biconvex tablets in a PVC-PVdC/VMCH coated aluminium blister pack. On one side the tablets are embossed "AZ50" and have a score mark on the reverse.

Azathioprine AqVida 50 mg tablets are available in packs of 28, 30, 50, 56, 90 and 100 film-coated tablets.

Marketing Authorisation Holder:
[To be completed nationally]

Manufacturer
AqVida GmbH
Kaiser-Wilhelm-Str. 89
20355 Hamburg
Germany

PharmaSwiss d.o.o
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SLOVENIA

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