

Azaflam-K[®]

Azaflam-K 50 mg film-coated tablets (Diclofenac potassium)

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 **Azaflam-K** is and what it is used for.
2. What you need to know before you take **Azaflam-K**.
3. How to take **Azaflam-K**.
4. Possible side effects.
5. How to store **Azaflam-K**.
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1. What **Azaflam-K** is and what it is used for

Azaflam-K belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to reduce pain and inflammation in the following conditions:

- Sprains, strains and other injuries.
 - Pain and inflammation following surgery.
 - Gout.
 - Other painful conditions affecting the joints and muscles such as backache, rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and pyrophosphate arthropathy.
- The tablets can also be used to relieve the symptoms associated with migraine attacks in adults.

2. Before you take **Azaflam-K**

Do not take **Azaflam-K** if you:

- are allergic (hypersensitive) to diclofenac potassium or any of the other ingredients in the tablet (see section 6).
- have a peptic ulcer, in your stomach (gastric) or small intestine (duodenal) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation.
- have history of gastro-intestinal bleeding or perforation, relating to previous NSAID therapy.
- have previously had a reaction (asthma, hives or a cold) caused by an allergy to salicylates (e.g. aspirin) or other non-steroidal pain killers.
- suffer from severe kidney, heart or liver failure.
- have established heart disease and /or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages.
- have or have had problems with your blood circulation (peripheral arterial disease).
- are pregnant, and in the last three months (last trimester) of pregnancy.

Warnings and precautions

Check with your doctor or pharmacist before taking **Azaflam-K** tablets if you:

- have a history of gastrointestinal disease e.g. ulcerative colitis or Crohn's disease.
- have reduced heart, kidney, or liver function.
- suffer from any blood clotting disorder.
- have or have had asthma.
- suffer from liver porphyria (disorder of the red blood pigment).
- have had or need to have surgery.
- are elderly (over 65).
- are being treated with diuretics (water tablets) or COX-2 inhibitors such as celecoxib.

- have Systemic Lupus Erythematosus (SLE) and mixed connective tissue disease.

Make sure your doctor knows, before you are given **Azaflam-K**:

- If you smoke.
- If you have diabetes.
- If you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides.

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

Medicines such as diclofenac may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, have had a previous stroke or think that you might be at risk of these conditions you should discuss your treatment with your doctor or pharmacist.

Diclofenac may mask the signs and symptoms of infection. Whilst you are taking these tablets, your doctor may want to give you a check-up from time to time.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Especially:

- medicines to treat diabetes – a dose adjustment of these medicines may be necessary as blood sugar may drop too low.
- anticoagulants (e.g. warfarin) – these may increase the risk of bleeding.
- diuretics (water tablets) – the effect of these may be decreased. Potassium-sparing diuretics may increase the potassium levels in the blood.
- lithium (medicine to treat depression) the blood levels of these medicines may be increased if taken with Diclofenac.
- cytotoxic medicines (e.g. methotrexate to treat cancers) – should not be taken less than 24 hours before or after **Azaflam-K** tablets - the blood levels of these medicines may be increased if taken with Diclofenac.
- ciclosporin – this may harm kidney function.
- quinolones (to treat infections, e.g. ciprofloxacin and levofloxacin) – these may cause convulsions (fits).
- steroid tablets – these may increase the risk of bleeding in the stomach.
- other NSAIDs (e.g. aspirin) – these may increase the risk of side effects.
- medicines to treat high blood pressure (ACE-inhibitors, beta blockers) – the blood pressure lowering effect may be reduced.
- mifepristone (used to induce abortion) – effect of mifepristone may be reduced by NSAIDs.
- cardiac glycosides (e.g. digoxin) used to treat heart failure. Use with Diclofenac may worsen heart failure or increase blood levels of these medicines.
- tacrolimus (an immunosuppressant) - these may increase the risk of kidney damage.
- zidovudine (an antiretroviral drug used to treat HIV) - combination with Diclofenac may increase the risk of blood disorders.
- phenytoin (a medicine used to treat seizures) - the blood level of this medicine may be increased if taken with Diclofenac.
- colestipol and cholestyramine – these may reduce the effect of Diclofenac.
- potent CYP2C9 Inhibitors (e.g. sulfapyrazone and voriconazole) - the blood level of Diclofenac may be increased if taken with these medicines.
- selective serotonin reuptake inhibitors (SSRIs).
- trimethoprim.

Laboratory tests

Frequent liver and kidney function tests and monitoring of blood counts are necessary if taken for more than a few days.

Pregnancy and breastfeeding

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

Pregnancy

It is not recommended that you take **Azaflam-K** during the first 6 months of pregnancy.

However, your doctor may prescribe **Azaflam-K** for you during the first six months of pregnancy if he/she feels the benefit to you outweighs the risk.

You must not however take **Azaflam-K** during the last 3 months of pregnancy as damage to the foetus and reduced labour may occur.

Breastfeeding

You should only use **Azaflam-K** whilst breastfeeding if advised by your doctor.

Female fertility

Azaflam-K may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant

Driving and using machines

Some patients may experience side effects such as dizziness, drowsiness and visual disturbances which may affect their ability to drive or operate machinery. Make sure you are not affected before driving or operating machinery.

Important information about some of the ingredients :

This medicine contains 0.150 mmol (5.85mg) potassium per 50mg tablet. This should be taken into account if you have reduced kidney function or are on a controlled potassium diet.

3. How to take **Azaflam-K**

Always take **Azaflam-K** tablets exactly as your doctor has told you. If you are unsure check with your doctor or pharmacist. **Azaflam-K** tablets must not be taken long-term, blood tests should be carried out if taken for more than a few days.

To minimise side-effects, you should take the lowest effective dose for the shortest time necessary to relieve your symptoms.

The tablets must be swallowed whole with a glass of water, with or after food. The usual dose is:

- To treat pain and inflammation
- Adults - 75mg to 150mg a day in two or three doses.
- Elderly patients – a lower dose may be used. If you are frail or have a low body weight, your doctor may ask you to go back to see him regularly for the first 4 weeks of treatment, to make sure that you are not experiencing any side effects.
- Children aged 14 years and over – 75mg to 100mg daily, in two or three doses.
- Not recommended for children under 14 years old.

To treat the symptoms of migraine in adults

50mg taken when the first signs of a migraine attack appear. Another 50mg taken 2 hours after the first dose if needed and then every 4 to 6 hourly. You should not take more than 200mg in 24 hours.

These tablets are not suitable for the treatment of migraine in children.

If you take more **Azaflam-K** than you should:

Contact your doctor, emergency room or pharmacist if you have taken more **Azaflam-K** tablets than stated in this leaflet or more than what your doctor has prescribed (and you feel unwell).

If you forget to take **Azaflam-K**

Do not take a double dose to make up for forgotten dose. Continue the treatment as advised by your doctor.

4. Possible side effects

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

If you suffer from any of the following at any time during your treatment,

STOP TAKING the medicine and seek immediate medical help:

- pass blood in your faeces.
- pass black tarry stools.
- vomit any blood or dark particles that look like coffee grounds.
- an allergic reaction such as itching, low blood pressure, swelling of the face, lips, tongue, mouth and throat, which may cause shortness of breath or difficulty swallowing.
- a form of meningitis (aseptic) causing a combination of symptoms such as headache, fever, stiff neck, tiredness, muscle pain, sore throat and disorientation.
- yellowing of the skin or the whites of your eyes.
- stomach pain, indigestion, heartburn, wind, nausea (feeling sick), vomiting (being sick) or other abnormal stomach symptoms.
- any type of fit or seizure.
- an unexpected change in the amount of urine produced and/or its appearance.
- mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain (frequency not known, cannot be estimated from the available data).

Tell your doctor if you experience any of the following symptoms:

Common (affects up to 1 in 10 people):

headache, dizziness, 'spinning' sensation, feeling or being sick, diarrhoea, pain or swelling of your stomach or abdomen, indigestion, heartburn, wind, loss of weight or poor appetite, abnormal liver function tests, skin rashes.

Rare (may affect up to 1 in 1,000 people):

allergic reactions, tiredness, difficulty breathing, inflammation of the stomach, stomach ulcers or bleeding, vomiting blood, blood in the faeces, hepatitis, yellowing of the skin or whites of eyes, rash or raised lumps on your skin, fluid retention (symptoms of which include swollen ankles), drowsiness.

Very rare (may affect up to 1 in 10,000 people):

'pins and needles', tremor, blurred or double vision, hearing loss or impairment, tinnitus (ringing in the ears), difficulty sleeping, nightmares, depression, irritability, anxiety, psychotic reactions, disorientation, loss of memory, seizures, aseptic, meningitis, sensitivity to light, taste disturbance, constipation, inflammation of the tongue, mouth ulcers, ulcers of the gullet,

lower gut disorders (including inflammation of the colon causing diarrhoea and stomach pains), palpitations (fast or irregular heart beat), chest pain, high or low blood pressure, inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), congestive heart failure, blood disorders (including anaemia, making you tired and more prone to minor infections or bleeding), kidney or liver disorders or failure, presence of blood or protein in the urine, skin rash, itching, skin eruptions, eczema, dermatitis, Erythema Multiforme (round red patches on the skin), Stevens-Johnson-Syndrome (severe skin rash with flushing, fever, blisters and ulcers), or Lyell's Syndrome (severe rash with reddening, peeling and swelling of skin that looks like severe burns), hair loss, pancreatitis (inflammation of the pancreas), worsening of ulcerative colitis or Crohn's disease, impotence (difficulty getting an erection) angioneurotic odema (swelling of the skin).

Unknown (frequency cannot be estimated from the data):

neutropenia (can lead to low resistance to infections), confusion, hallucination, disturbances of sensation, generally feeling unwell, sudden loss of vision. Medicines such as **Azaflam-K** may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke (very rare).

5. How to store **Azaflam**

- Keep out of the reach and sight of children.
- Do not store above 30°C.
- Do not use after the expiry date stated on the carton. Unused tablets should be taken back to the pharmacist for safe disposal.
- Medicines should not be disposed via wastewater or household waste.
- Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What **Azaflam-K** contains

The active substance is diclofenac potassium.

Each tablet contains 50mg Diclofenac potassium.

The other ingredients are: microcrystalline cellulose, dibasic calcium phosphate, sodium starch glycolate, povidone, colloidal silicon dioxide, magnesium stearate.

What **Azaflam-K** looks like and contents of the pack

Azaflam-K tablets are brown, film-coated, bi-concave tablets.

They are supplied in packs containing 2 blisters, each blister contains 10 tablets.

Marketing Authorization holder and manufacturer:

Azal Pharma

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To report any Side effect
National Medicines and Poisons Board (NMPB)
Fax (+249)18532263
E-mail: info@nmpb.gov.sd
Website: www.nmpb.gov.sd

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consultation your doctor.
- Keep medication out of reach of children.

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Azal pharma.
Khartoum - Sudan

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