

Package leaflet: Information for the user**ALMIRAL 25mg gastro-resistant tablets****ALMIRAL 50 mg gastro-resistant tablets**

Diclofenac sodium

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 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 Almiral is and what it is used for
2. What you need to know before you take Almiral
3. How to take Almiral
4. Possible side effects
5. How to store Almiral
6. Contents of the pack and other information

1. What Almiral is and what it is used for

Diclofenac sodium, the active ingredient in Almiral tablets, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

Almiral tablets relieve pain, reduce swelling and ease inflammation in conditions affecting the joints, muscles and tendons including:

- Rheumatoid arthritis, osteoarthritis, acute gout, ankylosing spondylitis, psoriatic arthritis, arthritis due to crystal deposition.
- Backache, sprains and strains, soft tissue sports injuries, frozen shoulder, dislocations and fractures.
- Tendonitis, tenosynovitis, bursitis.
- Renal colic, migraine attacks and primary dysmenorrhea.

They are also used to treat pain and inflammation associated with dental and minor surgery.

Almiral 25mg tablets

Children (aged 1-12 years):

- Treatment of juvenile chronic arthritis.

2. What you need to know before you take Almiral

Do not take Almiral:

- If you are allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID or any of the other ingredients of this medicine (listed in section 6). Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic type reaction.
- If you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces).
- If you have had stomach or bowel problems after you have taken other NSAIDs.
- If you have severe heart, kidney or liver failure.
- If you 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
- If you have or have had problems with your blood circulation (peripheral arterial disease).
- If you are more than six months pregnant.

Warnings and precautions

Talk to your doctor or pharmacist before taking Almiral:

- If you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease.
- If you have kidney or liver problems, or are you elderly.
- If you have a condition called porphyria.
- If you suffer from any blood or bleeding disorder. If you do, your doctor may ask you to go for regular check-ups while you are taking these tablets.
- If you have or you ever had asthma or allergic rhinitis.

- If you are you breast feeding.
- If you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides.
- If you have heart problems, or have you had a stroke, or do you think you might be at risk of these conditions (for example, if you have high blood pressure, diabetes or high cholesterol or are a smoker.
- If you have diabetes.
- If you smoke.
- If you have Lupus (SLE) or any similar condition.
- If you may be dehydrated (e.g. due to illness, diarrhea or after an operation).
- If you have swelling in the legs.

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before receiving/taking/using Almiral, as diclofenac can sometimes worsen wound healing in your gut after surgery.

In very rare cases diclofenac, like all anti-inflammatory drugs, can cause serious allergic reactions (eg rash). If you experience such symptoms, tell your doctor immediately.

Other special warnings

- You should take the lowest dose of Almiral for the shortest possible time, particularly if you are underweight or elderly.
- There is a small increased risk of heart attack or stroke when you are taking any medicine like Almiral. The risk is higher if you are taking high doses for a long time. Always follow the doctor's instructions on how much to take and how long to take it for.
- Whilst you are taking these medicines your doctor may want to give you a check-up from time to time.
- If you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms.
- Because it is an anti-inflammatory medicine, Almiral may reduce the symptoms of infection, for example, headache and high temperature. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking Almiral.

Children

Almiral 50mg tablets are not suitable for children.

Almiral 25mg tablets can be administered to children aged between 1 and 12 years old.

Other medicines and Almiral

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can interfere with your treatment. Tell your doctor or pharmacist if you are taking any of the following:

- Medicines to treat diabetes.
- Anticoagulants (blood thinning tablets like warfarin).
- Diuretics (water tablets).
- Lithium (used to treat some mental problems).
- Methotrexate (for some inflammatory diseases and some cancers).
- Ciclosporin and tacrolimus (used to treat some inflammatory diseases and after transplants).
- Trimethoprim (a medicine used to prevent or treat urinary tract infections).
- Quinolone antibiotics (for infections).
- Any other NSAID or COX-2 (cyclo-oxygenase-2) inhibitor, for example aspirin or ibuprofen.
- Mifepristone (a medicine used to terminate pregnancy).
- Cardiac glycosides (for example digoxin), used to treat heart problems.
- Medicines known as SSRIs used to treat depression.
- Oral steroids (an anti-inflammatory drug).
- Medicines used to treat heart conditions or high blood pressure, for example beta-blockers or ACE inhibitors.
- Voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures).
- Colestipol/cholestyramine (used to lower cholesterol).

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 or pharmacist for advice before taking this medicine.

Do not take diclofenac if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take diclofenac during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or

while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, diclofenac can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Taking Almira! tablets may make it more difficult to conceive. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

Driving and using machines

Very occasionally people have reported that diclofenac have made them feel dizzy, tired or sleepy. Problems with eyesight have also been reported. If you are affected in this way, you should not drive or operate machinery.

Almira! contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Almira! also contains tartrazine aluminium lake (E102) and yellow FCF aluminium lake (E110).

May cause allergic reactions.

3. How to take Almira!

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

The doctor will tell you how much Almira! to take and when to take them. Always follow his/her instructions carefully. Keep taking your tablets for as long as you have been told, unless you have any problems. In that case, check with your doctor.

Take the tablets preferably before meals.

Swallow the tablets whole with a drink of water. Do not crush or chew the tablets.

The recommended dose is:

Adults

Dosage is individualized and depends on the patient's condition, indication and response of the patient.

The usual stating dose is 75-150mg daily in two or three divided doses.

The recommended maximum daily dose of diclofenac is 150mg.

Chronic maintenance administration is 50 to 100 mg daily in divided doses and its duration is determined by the treating physician depending on the patient's response. For the treatment of acute conditions, which require short-term treatment, pharmaceutical forms with rapid absorption are preferred.

Elderly

Your doctor may advise you to take a dose that is lower than the usual adult dose if you are elderly.

Your doctor may also want to check closely that the Almira tablets are not affecting your stomach.

Use in children

Almira 50mg tablets are not recommended for children.

Almira 25 mg tablets can be administered to children aged between 1 and 12 years old.

Children and adolescents should receive a total daily dose of 0.5 to 2 mg per kilogram of body weight, depending on the severity of their condition. The total daily dose should be divided into 2 to 3 doses. For the treatment of juvenile chronic arthritis the dose may be increased to a maximum of 3mg per kilogram of body weight given in divided doses.

The maximum daily dosage of 150mg should not be exceeded.

If you take more Almira than you should

If you, or anyone else, accidentally take too much, tell your doctor or your nearest hospital casualty department. Take your the medicine pack with you so that people can see what you have taken.

If you forgot to take Almira

If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, just take the next dose and forget about the one you missed . Do not take a double dose to

make up for a forgotten dose. Do not take more than 150 mg (three 50mg tablets or six 25mg tablets) in 24 hours.

4. Possible side effects

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

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

If you experience any of the following serious side effects, stop taking ALMIRAL and seek medical treatment or call your doctor immediately:

- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick).
- Any sign of bleeding in the stomach or intestine for example, when emptying your bowels, blood in vomit or black, tarry faeces.
- Allergic reactions which can include skin rash , itching, bruising, painful red areas, peeling or blistering.
- Wheezing or shortness of breath (bronchospasm).
- Swollen face, lips, hands or fingers.
- Yellowing of your skin or whites of your eyes.
- Persistent sore throat or high temperature.
- An unexpected change in amount of urine produced and/or its appearance.
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with diclofenac and followed by rectal bleeding or bloody diarrhea usually within 24 hours of the onset of abdominal pain (frequency not known, cannot be estimated from the available data).
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor.

The side effects listed below have also been reported.

Common side effects (may affect up to 1 in 10 people):

- Stomach pain, heartburn, nausea, vomiting, diarrhea, indigestion, wind, loss of appetite.

- Headache, dizziness, vertigo
- Skin rash or spots
- Raised levels of liver enzymes in the blood

Rare side effects (may affect up to 1 in 1000 people) :

- Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly).
- Gastritis (inflammation, irritation or swelling of the stomach lining).
- Vomiting blood.
- Diarrhea with blood in it or bleeding from the back passage.
- Black, tarry faeces or stools.
- Drowsiness, tiredness.
- Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock).
- Hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness).
- Skin rash and itching.
- Fluid retention, symptoms of which include swollen ankles.
- Liver function disorders, including hepatitis and jaundice.
- Asthma (including shortness of breath)
- Edema.

Very rare side effects (may affect up to 1 in 10000 people):

- Tingling or numbness in the fingers, paresthesia, tremor, visual disturbances such as blurred vision, blurred or double vision, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, mental disorders, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck, disturbances in sensation, aseptic meningitis, stroke.
- Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, taste changes, lower gut disorders (including inflammation of the colon, or worsening of ulcerative colitis or Crohn's disease), esophageal disorders, narrowings of the intestine resembling diaphragms, pancreatitis.

- Palpitations (fast or irregular heart beat), chest pain, hypertension (high blood pressure), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis) heart disorders, including congestive heart failure, blood disorders (including anaemia), thrombocytopenia, leukopenia, agranulocytopenia.
- Kidney or severe liver disorders including liver failure, presence of blood or protein in the urine, nephrotic syndrome, interstitial tubule nephritis, renal follicular necrosis.
- Serious skin rashes including Stevens-Johnson syndrome and Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight, exfoliative dermatitis, photosensitivity reactions, purpura, Henoch-Schonlein purpura, urticaria.
- Hair loss.

Uncommon side effects (may affect may affect between 1 and 10 in every 1000 people)*:

- Palpitations, chest pain, heart failure, myocardial infarction

**Frequency reflects data from long-term high-dose therapy (150 mg/day).

Data from clinical trials and epidemiological studies indicate that the use of diclofenac, particularly in high doses (150 mg daily) and in long-term treatment, may be associated with a small increase in the risk of thrombotic arterial events (for example, myocardial infarction or stroke).

Other side effects that have also been reported include:

- Inflammation of the pancreas, impotence. Facial swelling, inflammation of the lining of the brain (meningitis), confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves of the eye.
- Chest pain, which may be an indication of a potentially serious allergic reaction known as Kounis syndrome.
- Ischemic colitis.

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 the national reporting system: ADR Reporting: Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Almiral

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 carton and on the blister. The expiry date refers to the last day of that month.

Store below 25°C. Keep it in the original package.

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

6. Contents of the pack and other information

What Almiral contains

- The active substance is diclofenac sodium. Each Almiral 25 mg tablet contains 25 mg of the active ingredient diclofenac sodium. Each Almiral 50 mg tablet contains 50 mg of the active ingredient diclofenac sodium.
- The other ingredients are:

Almiral 25 mg tablets: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, silica colloidal anhydrous, magnesium stearate, propylene glycol, talc, simeticone, methacrylic acid copolymer, hydroxypropylmethylcellulose, tartrazine aluminium lake (E102), polyethylene glycol 8000, sunset yellow FCF aluminium lake (E110).

Almiral 50 mg tablets: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, silica colloidal anhydrous, magnesium stearate, propylene glycol, talc, simeticone, methacrylic acid copolymer, hydroxypropylmethylcellulose, tartrazine aluminium lake (E102), polyethylene glycol 8000, sunset yellow FCF aluminium lake (E110).

What Almiral looks like and contents of the pack

Almiral 25 mg tablets are orange, round, convex enteric coated tablets, with diameter of nucleus 7.0 mm.

Almiral 50 mg tablets are orange, round, convex enteric coated tablets, with diameter of nucleus 9.5 mm.

Almiral 25 mg tablets are supplied in aluminium/polyvinylchloride blisters of ten tablets in packs of three or ten blisters.

Almiral 50 mg tablets are supplied in aluminium/polyvinylchloride blisters of ten tablets in packs of two, three or ten blisters. Polyvinylchloride securitainers of 500 or 1000 tablets are also available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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