

Airtal 100 mg

Film-coated tablets

Aceclofenac

Composition per tablet

Aceclofenac (INN)100 mg
Excipients: microcrystalline cellulose, croscarmellose sodium, glyceryl palmitostearate, povidone, hydroxypropyl methyl cellulose, polyoxy 40 stearate and titanium dioxide.

Pharmaceutical form and contents of the container

Film-coated tablets for oral administration. Packages of 10, 20, 40 and 100 tablets.

Pharmacological properties

Aceclofenac is a synthetic non-steroidal product with significant analgesic and anti-inflammatory properties.

Pharmacokinetic properties

After its oral administration, aceclofenac is rapidly and fully absorbed in the form of unaltered drug. Peak plasma concentrations are reached approximately 1.25 to 3.0 hours after ingestion. Aceclofenac enters synovial fluid, where its concentrations reach approximately 57% of those in plasma. The volume of distribution is approximately 25 litres. The plasma half life is around 4 hours. Aceclofenac binds to proteins to a large extent (>99%). Aceclofenac circulates primarily in the form of unaltered drug. The principal metabolite detected in plasma is 4'-hydroxyaceclofenac. Approximately two thirds of the administered dose is excreted in urine, basically in the form of hydroxymetabolites.



No changes in the pharmacokinetics of aceclofenac have been detected in the elderly.

Pharmacodynamic properties

The mechanism of action of aceclofenac is largely based on prostaglandin synthesis inhibition. Aceclofenac is a potent inhibitor of the cyclooxygenase enzyme, which is involved in prostaglandin production.

Therapeutic indications

Treatment of inflammatory and painful processes such as low-back pain, odontalgia,

scapulohumeral periarthritis and extra-articular rheumatism, and for the chronic treatment of arthrosis, rheumatoid arthritis and ankylosing spondylitis.

Contraindications

Do not take Airtal:

- if you are in the third trimester of pregnancy or are breastfeeding your child.
- if you are allergic (hypersensitive) to aceclofenac or any of the other components in the product.
- if acetylsalicylic acid or other non-steroidal anti-inflammatory drugs have caused you asthma, rhinitis or urticaria or another allergic reaction.
- if you have had a stomach or duodenal haemorrhage or ulcer or a perforation of the digestive tract.
- if you have haemorrhages or blood disorders.
- if you have severe renal impairment.
- if you have severe hepatic impairment.
- if you suffer from severe heart failure.

Precautions for use

Take special care with Airtal:

- if you plan to become or believe that you could be pregnant.
- if you have had or are developing an ulcer, haemorrhage or perforation in the stomach or duodenum, which could present through intense or persistent abdominal pain and/or black faeces or even have no previous warning symptoms.

This risk is greater when high doses and long-term treatments are used, in patients with a history of peptic ulcer and in the elderly. In these cases, your doctor will consider the possibility of adding a stomach protector agent.

- if you have a liver condition.
- if you suffer from renal impairment.
- if you have heart problems or have had a cerebral attack (stroke, haemorrhage).

Medicines like Airtal can be associated to a moderately increased risk of heart ("myocardial infarctions") or cerebral attacks. This risk is more likely with high doses and long-term treatments. Do not exceed the recommended dose and duration of treatment.

If you have cardiac problems, a history of cerebral accidents, or believe that you could be at risk of suffering these conditions (for instance, if you have high blood pressure, diabetes, high cholesterol or smoke), you should consult your doctor or pharmacist about this treatment.

This type of medicines can also cause fluid retention, especially in patients with heart failure and/or high blood pressure (hypertension).

- if you have had clotting problems (you bled easily).
 - **Tell your doctor** if you are simultaneously taking medicines that alter blood clotting such as corticosteroids, oral anticoagulants or platelet antiaggregants such as acetylsalicylic acid. Also inform him or her of the use of other medicines that could increase the risk of haemorrhage such as corticosteroids and selective serotonin reuptake inhibitor antidepressants.
 - if you have Crohn's disease or ulcerative colitis, as medicines like Airtal can make these conditions worse.
 - if you are convalescing from an important surgical operation.
- Consult your doctor even if any of the above circumstances has affected you only once.

Warnings

Pregnancy and lactation

As the administration of medicines like Airtal has been associated to an increased risk of birth defects/miscarriages, its use is not recommended in the first and second trimesters of pregnancy unless it is absolutely necessary. In these cases, the dose and duration will be the lowest possible. The administration of Airtal is contraindicated in the third trimester.

Patients of childbearing age should consider that medicines like Airtal have been associated to a reduced ability to conceive.

Airtal should not be taken in breastfeeding.

Effects on ability to drive and use machines

If you faint or suffer from vertigo or other central nervous system disorders, do not drive or use dangerous tools or machinery while you are taking Airtal.

Use in the elderly

Precautions should be taken when treating elderly patients, who in general are more likely to suffer from undesirable effects, present cardiovascular, kidney or liver function disorders or receive concomitant medication.

Interactions

Tell your doctor or pharmacist if you are using, or have recently used, other medicines, including over-the-counter medication.

Some medicines can interact with Airtal. In these cases, it may be necessary to change the dose or interrupt the treatment with one of the medicines.

This is particularly important if you are taking lithium, digoxin, diuretics, antihypertensive agents, anticoagulants, platelet antiaggregants, hypoglycaemic agents, methotrexate, corticosteroids, acetylsalicylic acid or other non-steroidal anti-inflammatory drugs, selective serotonin reuptake inhibitors (SSRI antidepressants), cyclosporins, mifepristone, tacrolimus or zidovudine.

Incompatibilities

None have been described.

Posology and method of administration

Adults: 200 mg per day, in two 100 mg doses, one tablet in the morning and another at night.

Children: there is no clinical data on the use of Airtal in children, so its use in this population is not recommended.

Elderly patients: your doctor will tell you how much to take and should perform periodic controls.

Renal impairment or heart failure: your doctor will tell you how much to take and should perform periodic controls.

Liver impairment: in patients with liver conditions, the dose of Airtal should be reduced to 100 mg/day.

Instructions for the correct administration of the preparation

The tablets should be swallowed whole with plenty of liquid. They can be taken with food, as the degree of absorption of aceclofenac remains unaltered.

Overdose

No information is available about the consequences of an Airtal overdose in humans. In case of accidental overdose, the drug's absorption should be prevented by gastric lavage and treatment with activated charcoal.

It should be treated from a symptomatic perspective, combating gastrointestinal irritation, renal impairment, hypotension, respiratory distress and convulsions.

Undesirable effects

Like all medicines, Airtal can cause undesirable effects, although not everybody gets them. Most of them are mild and disappear when the medication is stopped.

The undesirable effects that can appear with Airtal consist of:

Common (affecting from 1 to 10 of every 100 patients)

- Gastric discomfort, abdominal pain, nausea and diarrhoea.
The most common undesirable effects occurring with medicines like Airtal (NSAIDs) are gastrointestinal: peptic ulcers, perforations (fatal, in some cases), particularly in the elderly.
- Dizziness.
- Elevated liver enzymes.

Uncommon (affecting from 1 to 10 of every 1000 patients)

- Gas, inflammation of the stomach, constipation, vomiting and mouth ulcers.
- Itching, rash and inflammation of the skin (dermatitis).
- Elevated urea, elevated creatinine.

Rare (affecting from 1 to 10 of every 10000 patients)

- Blood in the faeces.
- Facial swelling.
- Heart failure, high blood pressure.
Medicines like Airtal can be particularly associated to a moderately increased risk of suffering a heart ("myocardial infarction") or cerebral attack.
- Anaemia.
- Severe allergic reaction, allergies.
- Sight disorders.
- Breathing difficulties.

Very rare (affecting less than 1 out of every 10000 patients)

• Inflammation of the mucous membrane of the mouth, digestive haemorrhage, inflammation of the pancreas, intestinal perforation.

Cases of ulcerative colitis and Crohn's disease have been seen to get worse.

- Purplish blemishes on the skin, severe skin reactions.
On very rare occasions, medicines like Airtal can be associated to very severe skin blistering reactions such as Stevens-Johnson syndrome and Toxic Epidermal Necrolysis.
- Palpitations, reddening of the skin, heat, liquid retention (oedemas).
- Liver damage (including hepatitis).
Medicines like Airtal can be associated to liver disorders causing yellowing of the skin and eyes,

occasionally with high fever or swelling and sensitivity of the upper abdomen. Suspend the treatment and tell your doctor IMMEDIATELY if you notice jaundice (yellowing) of the skin or eyes.

- Reduced white blood cells, reduced platelets, bone marrow depression, haemolytic anaemia.
- Increased blood potassium.
- Depression, sleep disorders, difficulty falling asleep.
- Tingling sensation, drowsiness, headache, taste disorders, tremors.
- Vertigo.
- Wheezing, bronchospasm.
- Leg cramps.
- Altered kidney function (nephrotic syndrome), renal impairment.
- Fatigue, liquid retention (oedema).
- Elevated alkaline phosphatase, weight gain.
Tell your doctor or pharmacist if you believe that you suffer from a serious undesirable effect or notice an effect not mentioned here.

Shelf life

This medication should not be used after the expiry date specified on the container.

Storage instructions

Store below 30°C.

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 the 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 consulting your doctor.
- Keep medicament out of the reach of children.

Council of Arab Health Ministers - Union of Arab Pharmacists

Under medical prescription

Keep medicines out of the reach and sight of children

Manufacturer

Industrias Farmacéuticas Almirall, S.L.
Ctra. Nacional II, Km. 593
08740 Sant Andreu de la Barca – Barcelona (Spain)

Marketing Authorisation Holder

Almirall, S.A.
General Mitre, 151
08022 Barcelona (Spain)

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