

Airtal[®] 100mg film-coated tablet

Aceclofenac (100mg)

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What *Airtal* is used for

Airtal is used to relieve pain and reduce redness and swelling (inflammation) in patients suffering from:

- Osteoarthritis - inflammation of the joints. This is a common condition in patients over the age of 50 and causes damage to the tissues and bones in the joints.
- Rheumatoid arthritis - long term inflammation of the joints caused by the body's own immune system (autoimmune response).
- Ankylosing spondylitis - inflammation of the spine/backbone which can lead to the joints fusing together.

How *Airtal* works

Airtal belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). They have anti-inflammatory and painkiller properties causing a lowering of swelling, redness (inflammation) and pain. The medicine/active ingredient of *Airtal* is aceclofenac.

Airtal works by blocking the production of hormone-like substances called prostaglandins. Prostaglandins have many functions in the body including an important role in both the way the body responds to inflammation and also the reabsorption of calcium in some diseases of the bone.

Before you use *Airtal*

- When you must not use it

- if you are allergic to aceclofenac or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to aspirin or any other NSAIDs (such as ibuprofen, naproxen or diclofenac).
- if you have taken aspirin or any other NSAIDs and experienced one of the following:
 - asthma attack causing tightness in the chest wheezing and difficulty breathing.
 - runny nose, itching and/or sneezing (irritation of the nose).
 - raised red circular patchy rash on the skin which may have felt itchy or like a sting or burn.
 - a severe allergic reaction known as anaphylactic shock. The symptoms may be life threatening and include difficulty breathing, wheezing, abdominal pain and vomiting.
- if you have a history of, suffer from, or suspect that you have a stomach ulcer or have vomited blood or passed blood in your faeces (black tarry stools).
- if you have severe kidney disease.
- if you have established heart disease and/or cerebrovascular disease e.g. if you have had a heart attack, stroke, cerebrovascular accident, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages or an intervention for restoring a circulatory structure, or if you are suffering from congestive heart failure or from an uncontrolled hypertension (high blood pressure).
- if you have or have had problems with your blood circulation (peripheral arterial disease).
- if you suffer from, or suspect that you have severe liver failure.
- if you suffer from bleeding or any type of blood clotting disorders.

- if you are pregnant (unless your doctor considers it essential for you to continue to take this medicine)

Airtal is not recommended for use in children.

Pregnancy and lactation

Do not take *Airtal* 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 *Airtal* 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, *Airtal* 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.

- Before you start to use it

Before you start taking *Airtal*, tell your doctor:

- if you suffer from any other form of kidney or liver disease.
- if you have any of the following disorders, as they may worsen:
 - Disorders of the stomach or gut/bowel
 - inflammatory bowel disease (ulcerative colitis)
 - chronic inflammatory bowel disease (Crohn's disease)
 - ulceration, bleeding or perforation of the stomach or bowel

- if you have, or have ever had problems with the circulation of the blood to your brain.
- If you suffer from asthma or any other breathing problems
- if you suffer from a rare inherited disorder known as **porphyria**.
- if you smoke
- if you have diabetes
- if you have angina, blood clots, high blood pressure, raised cholesterol or or other raised body fats such as triglycerides
- if you suffer from an autoimmune condition known as systemic lupus erythematosus or other connective tissue disorders.
- if you are infected with chicken pox, the use of this medicine should be avoided because a rare serious infection of the skin may develop.
- if you are recovering from major surgery.
- if you are elderly (your doctor will prescribe you the lowest effective dose over the shortest duration).

Hypersensitivity reactions can occur and very rarely, very serious allergic reactions are appearing (see section 4. Possible side effects). The risk is higher in the first month of treatment. Airtal should be stopped immediately at the first onset of symptoms such as tightness of the chest, breathing difficulties, fever, skin rashes, soreness of the skin lining the mouth and other mucous membranes causing ulcers, or any signs of hypersensitivity.

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

- Taking other medicines

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

Please tell your doctor if you are taking:

- medicines used to treat mental health problems like **depression**

(selective serotonin-reuptake inhibitors (SSRIs) such as citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine and sertraline) or manic depression (lithium)

- medicines used to treat **heart** failure and irregular heart beats (cardiac glycosides such as digoxin)
- medicines used to treat high blood pressure (antihypertensives: ACE inhibitors such as enalapril, lisinopril; angiotensin II receptor antagonists such as losartan, candesartan; also hydralazine, methyldopa, clonidine, moxonidine, propranolol)
- medicines to treat infection (**quinolone antibiotics** such as ciprofloxacin, ofloxacin, levofloxacin, moxifloxacin)
- drugs used to increase the rate of **urine excretion** (diuretics such as thiazides, furosemide, amiloride hydrochloride)
- medicines that stop **blood** clotting (anticoagulants) such as warfarin, heparin
- methotrexate which is used to treat **cancer** and **autoimmune** disorders such as arthritis and skin conditions
- mifepristone
- any **steroids** for the treatment of swelling and inflammation (glucocorticoids such as hydrocortisone, prednisolone,)
- medicines used to suppress the **immune** system after organ transplant (cyclosporin or tacrolimus)
- medicines used to treat HIV (zidovudine)
- medicines used to lower blood **sugar** levels in diabetes (antidiabetics such as glibenclamide, glicazide, tolbutamide)
- any other painkiller **NSAID** drugs (aspirin, ibuprofen, naproxen, COX-2 inhibitors such as celecoxib and etoricoxib)
- antiplatelet drugs such as clopidogrel.

How to use Airtal

- How much to use

Always take this medicine exactly as your doctor or pharmacist has told you. You will be prescribed the lowest effective dose over the shortest duration to reduce side effects. Check with your doctor or pharmacist if you are not sure.

The recommended dose in adults is 200mg (two Airtal tablets). One 100mg tablet should be taken in the morning and one in the evening.

Tablets should be swallowed whole with plenty of water and should be taken with or after food. Do not crush or chew the tablets.

Do not exceed the stated daily dose.

Elderly

If you are elderly, you are more likely to experience serious side-effects (listed in section 6 'Side Effects'). If your doctor prescribes Airtal for you, you will be given the lowest effective dose over the shortest duration of treatment.

- When to use it

Airtal must be taken preferably with or after food.

Use as directed by your doctor or pharmacist.

- How long to use it

Continue using Airtal for as long as your doctor recommends.

- If you forget to use it

If you miss a dose, do not worry, just take the next dose at the usual time. Do not take a double dose to make up for a forgotten tablet dose.

- If you use too much (overdose)

If you accidentally take too many Airtal tablets, contact your doctor immediately or go to your nearest hospital casualty department. Please take this leaflet or the box the Airtal tablets came in, with you to the hospital so that they will know what you have taken.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Airtal*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking *Airtal* unless your doctor advises you.

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

- Things to be careful of

Driving and using machines

If you are taking *Airtal* and you experience dizziness, drowsiness, vertigo, tiredness or any difficulty with your eyesight, you must not drive or use machinery.

Side effects

Like all medicines, Aceclofenac (*Airtal*®) can cause side effects, although not everybody gets them.

The side effects which may appear with Aceclofenac (*Airtal*®) are:

Common (affecting up to 1 in every 10 people)

- Gastrointestinal distress, abdominal pain, nausea and diarrhoea.
- Dizziness.
- Elevated liver enzyme levels.

Uncommon (affecting up to 1 in every 100 people)

• Wind, inflammation of the stomach, constipation, vomiting and mouth ulcers.

• Itching, skin rash, inflammation (dermatitis) and hives.

• Increased urea, increased creatinine.

Rare (affecting up to 1 in every 1,000 people)

• Blood in the stools, gastrointestinal bleeding, gastrointestinal ulcer.

• Swelling of the face, tongue or throat (angioedema).

• Heart failure, raised blood pressure.

• Anaemia.

• Severe allergic reaction, allergies.

• Visual disturbances.

• Difficulty breathing.

Very rare (affecting up to 1 in every 10,000 people)

• Inflammation of the mucous membranes in the mouth, inflammation of the pancreas, intestinal perforation, vomiting with blood, worsening of ulcerative colitis and Crohn's disease.

• Purplish blotches on the skin, severe skin reactions.

On very rare occasions, medicines like Aceclofenac (*Airtal*®) may be associated with very severe reactions affecting the skin and mucous membranes such as Stevens-Johnson syndrome and toxic epidermal necrolysis.

• Palpitations, warmth and redness of the face (flushing), hot flushes, inflammation of the blood vessels (vasculitis).

• Liver damage (including hepatitis), increased alkaline phosphatase. Medicines like *Airtal*® may be associated with liver disorders that cause the skin and eyes to turn yellow, sometimes with high fever or swelling and sensitivity of the upper abdomen. If you experience any of the following reactions, stop the treatment and tell your doctor IMMEDIATELY: yellowing of skin or eyes.

• Reduced white blood cell count, reduced platelet count, reduced neutrophil count, bone marrow depression, haemolytic anaemia.

• Increased potassium in the blood.

• Depression, abnormal dreams, trouble falling asleep (insomnia).

• Tingling, drowsiness, headache, altered sense of taste, tremors.

• Vertigo, ringing in the ears (tinnitus).

• Noisy breathing, bronchospasm.

• Leg cramps.

• Impaired kidney function (nephrotic syndrome), kidney failure.

• Fatigue, fluid retention (oedema).

• Weight gain.

Severe skin infections have occurred on very rare occasions in patients with chickenpox.

You may report any side effects or adverse drug reactions directly to the National Centre for adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of *Airtal*

- Storage

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

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the outer carton. The expiry date refers to the last day of that month. It is recommended that you store *Airtal* in the original box

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Airtal 100 mg film-coated tablets are white, round tablets.

- Ingredients

- Active ingredient(s)

The active substance is aceclofenac 100mg.

- Inactive ingredients

The other ingredients (excipients) are:

Tablet core - microcrystalline cellulose, sodium croscarmellose, povidone and glyceryl palmitostearate.

Coating Material - partially substituted hydroxypropyl methylcellulose, microcrystalline cellulose, polyoxyethylene 40 stearate and titanium dioxide (E171).

- MAL number:

MAL20026048AZ

Manufacturer

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