Airtal®

(Aceclofenac)

Highnoon

COMPOSITION
Airtal 100mg Tablet: Each film-coated tablet contains:
Aceclofenac 100mg

DESCRIPTION
Airtal (Aceclofenac) is a non-steroidal agent with excellent anti-inflammatory and analgesic properties.

MECHANISM OF ACTION
The mode of action of aceclofenac is largely based on the inhibition to prostaglandin synthesis. Aceclofenac is a potent inhibitor of the enzyme cyclo-oxygenase, which is involved in the production of prostaglandins. In addition to the inhibition of prostaglandin synthesis, aceclofenac inhibits pro-inflammatory mediators, decreases adhesion molecules expressions, inhibits Nitric Oxide production and shows antioxidant properties all these contribute to its strong ant inflammatory property.

PHARMACOKINETICS
Aceclofenac is well absorbed from the gastrointestinal tract and peak plasma concentration occurs 1 to 3 hours after an oral dose. Aceclofenac is more than 99% bound to plasma proteins. The plasma elimination half-life is about 4 hours. About two-thirds of a dose is excreted in the urine, mainly as hydroxymetabolites.

INDICATIONS AND USAGE
It is used to relieve pain and inflammation in patients suffering from:
- Osteoarthritis,
- Rheumatoid arthritis and
- Ankylosing spondylitis

DOSAGE AND ADMINISTRATION
The tablets are supplied for oral administration and should be swallowed whole with a sufficient quantity of liquid. It should be taken preferably with or after food.
Adults:
The recommended dose is 200 mg daily, taken as two separate 100 mg doses, one tablet in the morning and one in the evening.
Children:
It is not recommended for use in children under the age of 18 years.
Elderly:
The pharmacokinetics of Aceclofenac are not altered in elderly patients, therefore it is not considered necessary to modify the dose or dose frequency. As with other non-steroidal anti-inflammatory drugs (NSAIDs), caution should be exercised in the treatment of elderly patients, who are at increased risk of the serious consequences of adverse reactions, and who are more likely to be suffering from impaired renal, cardiovascular or hepatic function and receiving concomitant medication. If an NSAID is considered necessary, the lowest effective dose should be used for the shortest possible duration. The elderly should be monitored regularly for GI bleeding during NSAID therapy.

CONTRAINDICATIONS

- Hypersensitivity to any of the constituents.
- NSAIDs are contraindicated in patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema or urticaria) in response to ibuprofen, aspirin, or other non-steroidal anti-inflammatory drugs.
- Hepatic failure.
- Renal failure.
- Congestive heart failure (NYHA II-IV), ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease.
- Active or previous peptic ulcer.
- History of upper gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.
- Pregnancy, especially during the last trimester of pregnancy, unless there are compelling reasons for doing so. The lowest effective dosage should be used.

ADVERSE EFFECTS
The reported adverse events are; a small increased risk of heart attack, (myocardial infarction) or stroke, severe allergic reaction (anaphylactic shock),it may include (difficulty breathing, wheezing, abnormal pain and vomiting, skin rash, flaking skin, boils or sore lips and mouth), bullous reactions including Stevens Johnson Syndrome, Toxic epidermal necrolysis, photosensitivity, thrombocytopenia, vasculitis, neutropenia, granulocytopenia, hyperkalemia, paraesthesia, somnolence, dysgeusia, vertigo, tinnitus, bronchospasm, stridor, dyspepsia & nephrotic syndrome. The additional reported adverse events are; signs of allergic reaction may include sudden wheeziness fluttering or tightness in the chest and collapse, swelling of the face, kidney failure, interstitial nephritis, indigestion or heartburn, abdominal pain or other abnormal stomach symptoms, dizziness, nausea, diarrhoea, increased liver enzymes in the blood, flatulence, gastritis, constipation, vomiting, mouth ulcers, itching, rash, inflammation of the skin, dermatitis, raised circular red itchy, stinging or burning patches on the skin (hives), increase in blood urea levels, increase in blood creatinine levels, low levels of iron in the blood, hypersensitivity (allergic reaction), swelling, visual disturbance, shortness of breath, heart failure, high blood pressure, gastrointestinal (stomach) bleeding, gastrointestinal (stomach) ulcer, low white blood cells levels, low platelets levels in the blood, decreased bone marrow function, anaemia, agranulocytosis, high potassium levels in the blood, depression, strange dreams, inability to sleep, tingling, pricking or numbness of skin, tremor, drowsiness, headaches, abnormal taste in the mouth, sensation of spinning when standing still, heart pounding or palpitations, hot flushes, difficulty breathing, high pitched noise when breathing, inflammation of the mouth, stomach ulcer, pancreatitis, hepatitis, jaundice, spontaneous bleeding into the skin (appears as a rash), blisters, water retention and swelling, tiredness, leg cramps, increased blood alkaline phosphatase levels, weight gain, sound or ringing in the ears, redness, pain in a blood vessel, Crohn's disease, kidney failure, bone marrow failure, hallucinations, confusion, blurred, partial or complete loss of vision, painful movement of the eye, aggravated asthma, ulcers, perforation of either the stomach, large intestine or bowel wall, blistering and peeling of the top layer of skin, itchy pink/redness of the skin, reddening or scaling of skin, skin irritation (eczema), skin reaction to sunlight, aseptic meningitis, exacerbation of colitis, hypertension and cardiac failure,

Drug interactions
Drug interactions associated with aceclofenac are similar to those observed with other NSAIDs.
- Interactions involving NSAIDs include enhancement of the effects of oral anticoagulants (especially by azapropazone and phenylbutazone) and increased plasma concentrations of lithium, methotrexate, and cardiac glycosides.
- The risk of nephrotoxicity may be increased if given with ACE inhibitors, ciclosporin, tacrolimus or diuretics. Effects on renal function may lead to reduced excretion of some drugs.
- NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.
- There may also be an increased risk of hyperkalaemia with ACE inhibitors and some diuretics including potassium sparing diuretics.
- The antihypertensive effects of some antihypertensives including ACE inhibitors, beta blockers and diuretics may be reduced.
- Convulsions may occur due to an interaction with quinolones.
- NSAIDs may increase the effects of phenytoin and sulfonylurea antidiabetics.
- Use of more than one NSAID together (including aspirin) should be avoided because of the increase risk of adverse effects.
- The risk of gastrointestinal bleeding and ulceration associated with NSAIDs is increased when used with corticosteroids, the SSRIs, the SNRI venlafaxine, the antiplatelets clopidogrel and ticlopidine, iloprost, erlotinib, sibutramine, or possibly, alcohol, bisphophonates, or pentoxofylline.
- There may be an increased risk of haematotoxicity if zidovudine is used with NSAIDs. Ritonavir may have increased the plasma concentrations of NSAIDs.
- These have been occasional reports of increased adverse effects when NSAIDs were given with misoprostol although such combinations have sometimes been used to decrease the gastrointestinal toxicity of NSAIDs.
- The co-administration of Aceclofenac with other NSAID or corticosteroids may result in increased frequency of side effects.
- Caution should be exercised if NSAID and methotrexate are administered within 2-4 hours of each other, since NSAID may increase methotrexate plasma level, resulting in increased toxicity.

WARNINGS AND PRECAUTIONS
- Close medical surveillance is imperative in patients with symptoms indicative of gastrointestinal disorders, with a history suggestive of gastrointestinal ulceration, with ulcerative colitis or with Crohn's disease, bleeding diathesis or haematological abnormalities.
- Gastrointestinal bleeding or ulcerative perforation, haematemesis and melaena have in general more serious consequences in the elderly. They can occur at any time during treatment, with or without warning symptoms or previous history. In the rare instances, where gastrointestinal bleeding or ulceration occurs in patients receiving aceclofenac, the drug should be withdrawn. Close medical surveillance is also imperative in patients suffering from severe impairment of hepatic function. Aceclofenac should be given with caution to elderly patients with renal, hepatic or cardiovascular impairment and to those receiving other medication. The lowest effective dose should be used and renal function monitored regularly.
- As with other NSAIDs, allergic reactions, including anaphylactic/ anaphylactoid reactions, can also occur without earlier exposure to the drug.
- Caution should also be exercised in patients with history of coagulation defects and history of liver dysfunction.
- Renal and hepatic function and blood counts should be monitored during long term treatment. Persistently elevated hepatic enzyme levels necessitate withdrawal of aceclofenac.
- All NSAIDs are contraindicated in patients with active peptic ulceration or gastrointestinal bleeding; in addition, the non-selective NSAIDs should be used with caution, Pat all in patients with a history of such disorders.
- To reduce the risk of gastrointestinal effects, NSAIDs may be taken with or after food or Milk. Histamine H2- antagonist, proton pump inhibitors such as omeprazole, or misoprostol may be used for a similar purpose in high-risk patients taking non-selective NSAIDs.
- NSAIDs should be used with caution in patients with chronic disease or ulcerative colitis as these conditions may be exacerbated.
- All NSAIDs are contra-indicated in severe heart failure,
- NSAIDs should also be use with caution in patients in hypertension, left ventricular dysfunction, oedema or a history of cardiac failure , and in those with other risk factors for developing cardiovascular events.
- Other non-selective NSAIDs should be used with caution in uncontrolled hypertension, heart failure, ischemic heart disease, peripheral arterial disease, cerebrovascular disease and when used long term in patients with risk factors for cardiovascular events.
- NSAIDs should be used with caution in patients with infections, since symptoms such as fever inflammation maybe masked (for the suggestion that they should not be used in children with varicella see below).
- They should also be used with caution in patients with asthma allergic disorders.
- NSAIDs (including topical NSAIDs) are contra-indicated in patients with the history of hypersensitivity reactions to such drugs, including those in whom attacks of asthma, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other NSAIDs.
- Other general precautions to be observed include use in patients with haemorrhagic disorders, connective tissue disorders or impaired renal or haptic function.
- Patient undergoing therapy with some NSAID may need to be monitored for development of blood, kidney, liver or eye disorders.
- NSAID should be used with caution in the elderly and may need to be given in reduced doses.
- Patients with mild renal impairment should be kept under surveillance since the use of NSAIDs may result in deterioration of renal function. The lowest effective dose should be used and renal function monitored regularly.
- Dose of acedlofenac should be reduced in patients with impaired liver function. If abnormal liver function tests persist or worsen, clinical signs or symptoms consistent with liver disease develop or if other manifestations occur (eosinophilia, rash), aceclofenac should be discontinued. Hepatitis may occur without prodromal symptoms.

USE IN SPECIAL POPULATION

Pregnancy:
There is no information on use of aceclofenac in pregnant patients therefore the drug is not recommended in pregnant women.
Lactation:
Aceclofenac is not recommended in lactating women.

The use of Aceclofenac should be avoided in pregnancy and lactation unless the potential benefits to the other outweigh the possible risks to the foetus.

Fertility:
The use of Aceclofenac tablets may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility withdrawal of Aceclofenac tablets should be considered.

Paediatric use:
There are no clinical data on the use of aceclofenac in children.

OVERDOSAGE
The management of acute poisoning with NSAIDs essentially consists of supportive and symptomatic measures.

STORAGE & INSTRUCTIONS
To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30°C. Keep in a dry place. Protect from light.

PRESENTATION
Airtal 100mg Tablets:
Alu. Alu. Blister pack of 2 x 10's

ایئرٹال®

(اسیکلوفینک)

خوراک و ہدایات:

صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت اور استعمال کی جائے۔
بچوں کی پہنچ سے دور رکھیں۔ 30°C سے زیادہ درجہ حرارت پر نہ رکھیں۔
خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

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