SUMMARY OF PRODUCTS CHARACTERISTICS

1.NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : Riha Tablet

1.2 Generic Name : Aceclofenac Tablets 100mg

1.3 Strength : 100mg per tablet

1.4 Pharmaceutical Form : Tablet

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Each film-coated tablet contains:

Aceclofenac BP 100 mg

Colour: Sunset Yellow FCF & Titanium Dioxide BP

3. PHARMACEUTICAL FORM

Tablet

Orange coloured round shaped biconvex film-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Aceclofenac is indicated for relief from severe pain and inflammation in Osteoarthritis, Rheumatoid arthritis, Ankylosing spondylitis, Low back pain, Dental pain, Gynaecological pain and painful & inflammatory conditions of ear, nose & throat.

4.2 Posology and method of administration

The maximum recommended dose of Aceclofenac is 100 mg twice a day or as directed by the physician.

4.3 Contraindications:

Aceclofenac is contraindicated in active gastro-intestinal bleeding, active gastro-intestinal ulceration, cerebrovascular disease, history of gastro-intestinal bleeding related to previous NSAID therapy, history of gastro-intestinal perforation related to previous NSAID therapy, history of recurrent gastro-intestinal haemorrhage (two or more distinct episodes), history of recurrent gastro intestinal ulceration (two or more distinct episodes), ischaemic heart disease, mild heart failure, peripheral arterial disease & severe heart failure. It is also contraindicated in patients with a history of hypersensitivity to aspirin or any other NSAID-which includes those in whom attacks of asthma, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other NSAID.

4.4 Special warnings and special precautions for use:

Aceclofenac may cause allergic disorders, avoid in acute porphyrias, cardiac impairment (NSAID may impair renal function), coagulation defects, connective-tissue disorders, Crohn's disease (may be exacerbated), elderly (risk of serious side-effects & fatalities), history of cardiac failure, oedema, hypertension, left ventricular dysfunction, risk factors for cardiovascular events & ulcerative colitis (may be exacerbated). Long-term use of some NSAID is associated with reduced female fertility, which is reversible on stopping treatment.

Hepatic impairment: Initially 100 mg daily. Use with caution; there is an increased risk of gastrointestinal bleeding and fluid retention. Avoid in severe liver disease.

Renal impairment: Avoid if possible or use with caution; avoid in moderate to severe impairment. The lowest effective dose should be used for the shortest possible duration. In renal impairment monitor renal function; sodium and water retention may occur and renal function may deteriorate, possibly leading to renal failure.

4.5 Interaction with other FPPs and Other forms of Interaction

- **ACE Inhibitors:** Increased risk of renal impairment when NSAID given with ACE Inhibitors, also hypotensive effect antagonised.
- **Adrenergic Neurone Blockers:** NSAID antagonise hypotensive effect of Adrenergic Neurone Blockers.

- **Antiepileptics:** Possibly reduces excretion of Fosphenytoin and Phenytoin (increased risk of toxicity)**.**
- **Beta-blockers:** NSAID antagonise hypotensive effect of Beta-blockers.
- **Calcium-Channel Blockers:** NSAID antagonise hypotensive effect of Calcium-Channel Blockers.
- **Diuretics:** Risk of nephrotoxicity of NSAID increased by Diuretics and also antagonise effect of diuretic**.**
- **Vasodilator Antihypertensives:** NSAID antagonise hypotensive effect of Hydralazine, Minoxidil and Sodium Nitroprusside.

4.6 Pregnancy and lactation

Pregnancy: Avoid the use of NSAID during pregnancy or avoiding them unless the potential benefit outweighs the risk. NSAID should be avoided during the third trimester because use is associated with a risk of closure of fetal ductus arteriosus in utero and possibly persistent pulmonary hypertension of the newborn. In addition, the onset of labour may be delayed and its duration may be increased.

Breast feeding: Use with caution during breast-feeding.

4.7 Effects on ability to drive and use machines

Undesirable effects such as dizziness, vertigo, drowsiness, fatigue and visual disturbances are possible after taking NSAID. If affected, patients should not drive or operate machinery.

4.8 Side effects

Rare: Alveolitis-aseptic meningitis (patients with connective-tissue disorders such as systemic lupus erythematosus may be especially susceptible) hepatic damage, interstitial fibrosis associated with NSAID can lead to renal failure, pancreatitis, papillary necrosis associated with NSAID can lead to renal failure, pulmonary eosinophilia, Stevens-Johnson syndrome, toxic epidermal necrolysis and visual disturbances.

Frequency not known: Angioedema, blood disorders, bronchospasm, colitis (induction of or exacerbation of), Crohn's disease (induction of or exacerbation of), depression, diarrhoea, dizziness, drowsiness, fluid retention (rarely precipitating congestive heart failure) gastro-intestinal bleeding, gastro-intestinal disturbances, gastro-intestinal discomfort, gastro-intestinal ulceration, haematuria, headache, hearing disturbances, hypersensitivity reactions insomnia, nausea, nervousness, photosensitivity, raised blood pressure, rashes renal failure (especially in patients with pre-existing renal impairment) tinnitus & vertigo.

Serious side-effects: Cardiovascular, gastro-intestinal side-effects and a possible exacerbation of symptoms in asthma.

4.9 Overdose

Symptoms include headache, nausea, vomiting, epigastric pain, gastrointestinal irritation, gastrointestinal bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, hypotension, respiratory depression, fainting, occasionally and convulsions. In cases of significant poisoning acute renal failure and liver damage are possible.

Treatment: Patients should be treated symptomatically as required. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life threatening overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Analgesic; Anti-inflammatory

Mechanism of action:

Aceclofenac relieves pain and inflammation through a variety of mechanisms and in addition exerts stimulatory effects on cartilage matrix synthesis. It has higher anti-inflammatory action than conventional NSAIDs. It is a cytokine inhibitor. It works by blocking the action of a substance in the body called cyclo-oxygenase. Cyclo-oxygenase is involved in the production of prostaglandins (chemicals in the body) which cause pain, swelling and inflammation. It stimulates glycosaminoglycan synthesis in human osteoarthritis cartilage by inhibition of IL1ß and suppresses cartilage degeneration by inhibiting IL-1ß mediated promatrix metalloproteinase production and proteoglycan release.

5.2 Pharmacokinetic properties

Aceclofenac is well absorbed from gastrointestinal tract & peak plasma concentrations (Cmax) are reached in 1-3 hours after an oral dose. The drug is more than 99% bound to plasma proteins & the volume of distribution (Vd) is approximately 25 liters. The presence of food reduces the rate of absorption (increased tmax) but not the extent of absorption (Cmax or AUC). Aceclofenac is metabolized mainly to 4'-hydroxy-aceclofenac. The drug is eliminated primarily through renal excretion with 70-80% of administered dose found in urine as glucoronides and rest being excreted in faeces. The plasma elimination half life of Aceclofenac is approximately 4 hours.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

SN	Ingredients	Spec.
01.	Dibasic Calcium Phosphate	BP
02.	Starch (Maize)	BP
03.	Sodium Methyl Hydroxybenzoate	BP
04.	Sodium Propyl Hydroxybenzoate	BP
05.	Gelatin	BP
06.	Purified Talc	BP
07.	Sodium Starch Glycolate	BP
08.	Magnesium Stearate	BP
09.	Colloidal Anhydrous Silica	BP
10.	H.P.M.C. (15 cps)	BP
11.	Colour Titanium Dioxide	BP
12.	Lake Sunset Yellow FCF	IH
13.	Diethyl Phthalate	BP
14.	Polyethylene Glycol-4000	BP
15.	Dichloromethane	BP
16.	Methanol	BP
17.	Purified Talc	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at temperature not exceeding 30^0C. Keep away from moisture. Protect from light. Keep out of reach of children.

6.5 Nature and contents of container

10's x 10 Alu-Alu blister strips in an inner carton.
10's x 3 Alu-Alu blister strips in a mono pack.
10's x 20 Alu-Alu blister strips in an inner carton.
10's Alu-Alu blister strip in a mono pack & such 20 mono packs in an outer carton.
20's Alu-Alu blister strip in a mono pack & such 10 mono packs in an outer carton.

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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Country : INDIA

8. MARKETING AUTHORISATION NUMBER

06714/07510/REN/2020

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Oct 24, 2021

10. DATE OF REVISION OF THE TEXT

01/01/2023