

Product Name	Aceclofenac and Tizanidine Tablets	
Module 1	Administrative Information and Product Information	

1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product: Aceclofenac And Tizanidine Tablets

2. Qualitative and Quantitative composition:

Composition:

Each film coated tablet contains:

Aceclofenac BP 100 mg

Tizanidine Hydrochloride USP4 mg

Excipients q.s.

Colour: Titanium Dioxide BP

3. Pharmaceutical Form: Oral tablets.

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4. Clinical Particulars:

4.1 Therapeutic Indications:

Aceclofenac and Tizanidine Tablets are used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms:

- Spinal cord diseases
- Brain and nerve disorders
- Brain injury
- Rheumatoid arthritis
- Ankylosing spondylitis
- Osteoarthritis
- Periarthritis of scapulohumerous
- Lumbago
- Ischiadynia

4.2 Posology and method of administration:

Aceclofenac - Usual Dose: 100 mg twice daily.

Tizanidine hydrochloride may be prescribed with or without food. Once the formulation has been selected and the decision to take with or without food has been made, this regimen should not be altered.

The recommended starting dose is 2 mg. Because the effect of Tizanidine hydrochloride peaks at approximately 1 to 2 hours post-dose and dissipates between 3 to 6 hours post-dose, treatment can be repeated at 6 to 8 hour intervals, as needed, to a maximum of three doses in 24 hours.

Method of administration

Oral use.

4.3 Contraindications:

Hypersensitivity to Aceclofenac and Tizanidine Tablets is a contraindication. In addition, Aceclofenac and Tizanidine Tablets should not be used if you have the following conditions:

- Active peptic ulcer
- Acute rhinitis
- Alcohol

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- Allergy to Aceclofenac
- Asthma
- Breastfeeding

4.4 Special warning and precaution for use:

Before using Aceclofenac and Tizanidine Tablets, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- Avoid driving and operate dangerous machinery
- Do not drive or operate heavy machinery
- Do not stop the treatment immediately
- Gastro-intestinal disorders
- History of gastroulceration
- Patients recovering after a surgery

4.5 Interaction with other medicinal products and other forms of interaction:

Aceclofenac and Tizanidine Tablets are use with other drugs or over the counter products at the same time, the effects of Aceclofenac and Tizanidine Tablets may change. This may increase your risk for side-effects or cause your drug not to work properly.

Aceclofenac and Tizanidine Tablets are may interact with the following drugs and products:

- Albuterol
- Alcohol
- Alprazolam
- Aspirin
- Celecoxib
- Cholecalciferol

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4.6 Pregnancy and Lactation:

Pregnancy is always a special situation where every action or side effect of the drug varies when compared to a situation of a non-pregnant patient. It is not only because the pregnant woman's metabolism differs due to the hormonal and other changes happened to her, but also because every medicine or its metabolite passes to the baby and shows its action there. The only thing is, be cautious, attentive and well supervised when you take any single drug in pregnancy. The interactions can vary in pregnancy, and the dosage may differ as well. Strict supervision of the Physician is mandatory.

4.7 Effects on the ability to drive and use machines:

Dizziness is reported as a common reaction. Patients should be advised that if affected they should not drive, operate machinery or take part in activities where this could put them or others at risk.

4.8 Undesirable effects:

The following is a list of possible side-effects that may occur in medicines that contain Aceclofenac and Tizanidine Tablets. This is not a comprehensive list. These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away.

- Nausea
- Low blood pressure
- Slow heartbeat
- Sleepiness
- Increased liver enzyme
- Muscular weakness

4.9 Overdose:

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

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Treatment: Patients should be treated symptomatically as required. Within 1-hr of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within 1-hr of ingestion of a potentially life-threatening overdose. Good urine output should be ensured. Renal and liver function should be closely monitored. Patients should be observed for at least 4 hrs after ingestion of potentially toxic amounts. In case of frequent or prolonged convulsions, patients should be treated with diazepam IV. Other measures may be indicated by the patient's clinical condition. Specific therapies eg, dialysis or haemoperfusion are probable of no help in eliminating NSAIDs due to their high rate of protein-binding and extensive metabolism. Management of acute poisoning with NSAIDs essentially consists of supportive and symptomatic measures.

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5. Pharmacological Particulars:

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Nonsteroidal anti-inflammatory drugs (NSAIDs), Analgesic, Antiinflammatory, Anti arthritic.

ATC code:

Aceclofenac - M01AB16

Tizanidine - M03BX02

Mechanism of Action: Aceclofenac and Tizanidine Tablets improves the patient's condition by performing the following functions:

- Relaxing muscles and reducing pain.
- Blocking the action of cyclo-oxygenase in the body.

5.2 Pharmacokinetic properties

Aceclofenac

Absorption- It is rapidly and completely absorbed after oral administration

Distribution- Widely distributed in the body as protein-bound form. It is highly protein-bound (>99.7%). Aceclofenac penetrates into the synovial fluid, where the concentrations reach approximately 60% of those in plasma.

Metabolism- Metabolized into metabolites in the liver. Main metabolite is 4-hydroxyaceclofenac

Excretion- It is excreted through urine mainly as conjugated hydroxymetabolites

Tizanidine

Absorption- Completely absorbed after oral administration.

Distribution- Widely distributed throughout the body. 30% bound to the plasma proteins.

Metabolism- Metabolized in the liver to its metabolites.

Excretion- Excreted through urine.

5.3 Pre-clinical Safety:

Not Applicable

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6. Pharmaceutical Particulars:

6.1 List of Excipients:

- Sodium starch glycolate BP
- Maize starch BP
- Microcrystalline cellulose BP
- Povidone (P.V.P. K-30) BP
- Sodium Benzoate BP
- Crospovidone BP
- Colloidal anhydrous silica BP
- Purified Talc BP
- Stearic acid BP
- Isopropyl alcohol BP
- Dichloromethane BP

6.2 Incompatibilities: None

6.3 Shelf Life: 24 months.

6.4 Special Precautions for storage:

Store at below 30° C. Protect from light.

KEEP THE MEDICINE OUT OF REACH AND SIGHT OF CHILDREN

6.5 Nature and contents of container:

ALU-PVC Blister pack along with pack insert in a carton.

6.6 Special precautions for disposal and other handling

None

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7. Marketing Authorization Holder:

Ralphones Pharmaceutical Nigeria Limited
Ralphone Lane, Ikorodu, Lagos.

Manufacturer
Ratnatris Pharmaceuticals PVT. LTD,
Survey No 750/1, Ahmedabad, Mehsana
Highway, India.

8. Marketing Authorization Number:

NA

9. Date of first Authorization /renewal of the authorization:

NA

10. Date of revision of text:

NA