1.3.1

Summary of Product Characteristics (SmPC)

1. Name of the medicinal Product

1.1 Name of the medicinal Product

Aceclofenac Tablets 100 mg

1.2 Strength

Each Film Coated Tablets contains:

Aceclofenac BP	100 mg
Excipients	Q.S.

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

Aceclofenac BP

2.2 Quantitative Declaration

Sr. No.	Ingredients	Specifications	Standard Quantity/ml (mg)	Reason for Inclusion
01	Aceclofenac	BP	100.00	Analgesic & Anti-inflammatory
02	Microcrystalline Cellulose (Plain)	BP	152.083	Diluent
03	Maize Starch	BP	29.032	Binder
04	Povidone (PVPK-30)	BP	9.000	Disintegrant
05	Isopropyl Alcohol	BP	50.00	Solvent
06	Purified Talc	BP	5.000	Lubricant
07	Magnesium Stearate	BP	5.000	Lubricant
08	Croscarmellose Sodium	USP-NF	8.000	Disintegrant
09	Colour White SC-SP-3180 (Spraycel)	IH	9.000	Colouring Agent
10	Purified Water	BP	Q.S.	Solvent

3. Pharmaceutical Form

Film Coated tablets.

White to off-white coloured, round shaped, biconvex, film coated tablets, plain on both sides.

4. Clinical Particulars

4.1 Therapeutic Indications

Aceclofenac Tablet is indicated for the relief of pain and inflammation in osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

4.2 Posology and Method of Administration

Adults: The recommended dose is 200 mg daily, taken as two separate 100 mg doses, one tablet in the morning and one tablet in the evening.

Elderly: The pharmacokinetics of Aceclofenac is not altered in elderly patients, therefore it is not considered necessary to modify the dose or dose frequency..

4.3 Contraindications

Aceclofenac Tablet is contraindicated in the following situations:

Patients sensitive to Aceclofenac or to any of the excipients of the product.

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.

Patients with active or suspected peptic ulcer or gastrointestinal bleeding or bleeding disorders.

Patients with severe heart failure, hepatic or renal insufficiency.

Last trimester of pregnancy.

4.4 Special Warnings and Special Precautions for Use

Caution is required if administered to patients suffering from, or with a previous history of, bronchial asthma since NSAIDs have been reported to precipitate bronchospasm in such patients. GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious GI events.

In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis.

The use of Aceclofenac may impair female fertility and is not recommended in women attempting to conceive.

As with other NSAIDs, allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur without earlier exposure to the drug.

Aceclofenac may reversibly inhibit platelet aggregation.

Renal insufficiency: There is no evidence that the dosage of Aceclofenac needs to be modified in patients with mild renal impairment, but as with other NSAIDs caution should be exercised.

Hepatic insufficiency: There is some evidence that the dose of Aceclofenac should be reduced in patients with hepatic impairment and it is suggested that an initial daily dose of 100 mg be used.

4.5 Interaction with other medicinal products and other forms of interaction

Other analgesics including cyclooxygenase-2 selective inhibitors: Avoid concomitant use of two or more NSAIDs (including aspirin) as this may increase the risk of adverse effects.

Cardiac glycosides: Aceclofenac may exacerbate cardiac failure, reduce GFR (glomerular filtration rate) and increase plasma glycoside levels.

Methotrexate: Decreased elimination of methotrexate.

Ciclosporin: Increased risk of nephrotoxicity.

Corticosteroids: Increased risk of gastrointestinal ulceration or bleeding.

Anti-coagulants: Aceclofenac may enhance the effects of anti-coagulants, such as warfarin.

Zidovudine: Increased risk of haematological toxicity when Aceclofenac is given with zidovudine.

4.6 Fertility, Pregnancy and Lactation

The use of Aceclofenac may impair female fertility and is not recommended in women attempting to conceive.

4.7 Effects on ability To Drive and use Machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable Effects

The majority of adverse reactions reported have been reversible and of a minor nature.

Common side effects: Dyspepsia, Abdominal pain, Nausea, Diarrhea, Dizziness, Hepatic enzymes increased.

Uncommon side effects: Flatulence, Gastritis, Constipation, Vomiting, Mouth ulceration, Pruritus, Rash, Dermatitis, Urticaria.

Rare side effects: Anaemia, Visual disturbance, Dyspnoea

Very rare side effects: Granulocytopenia, Thrombocytopenia, Neutropenia, Haemolytic anaemia, Depression, Depression, Vertigo, Hepatitis, Oedema.

4.9 Overdose

Symptoms: Symptoms of overdose include headache, nausea, vomiting, epigastric pain, gastro intestinal irritation, gastrointestinal bleeding, rarely diarrhea, drowsiness, dizziness, hypotension, respiratory depression, fainting, occasionally 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 adult s, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose. Renal and liver function should be closely monitored. In case of frequent or prolonged convulsions, patients should be treated with intravenous diazepam.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Analgesic & anti-inflammatory.

Aceclofenac is an NSAID which directly blocks PGE 2 secretion at the site of inflammation by inhibiting IL- beta and TNF in the inflammatory cells. Aceclofenac has been demonstrated to inhibit cyclooxygenase (COX) activity and to suppress the PGE 2 production by inflammatory cells.

5.2 Pharmacokinetic Properties

Absorption: Aceclofenac is well absorbed from gastrointestinal tract and peak plasma concentrations (Cm.,) are reached 1-3 hours after an oral dose.

Distribution: The drug is more than 99% bound to plasma proteins and the volume of distribution (Vd) is approximately 25 liters. The presence of food reduced rate of absorption (increased tmax but not the extent of absorption (Cm.. or AUC) .

Metabolism and Excretion: 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 approximately 4 hours..

5.3 Preclinical Safety Data

Not Applicable

6 Pharmaceutical Particulars

6.1 List of Excipients

Microcrystalline Cellulose (Plain) BP

Povidone (PVPK-30) USP-NF

Maize Starch BP

Purified Talc BP

Crosscarmellose Sodium USP-NF

Magnesium Stearate BP

Colour White SC SP 3180 (Spraycel) IH

Isopropyl Alcohol BP (IPA)

Purified Water BP

6.2 Incompatibilities

None.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store below 30^0C. Protect from light.

6.5 Nature and Contents of Container

For 10 X 10 Pack: White to off-white coloured, round shaped, biconvex, film coated tablets, plain on both sides. 10 tablets are packed in Alu-Alu blister pack. 10 Blister packed in printed carton with packaging insert.

For 1 X 10 Pack: White to off-white coloured, round shaped, biconvex, film coated tablets, plain on both sides. 10 tablets are packed in Alu-Alu blister pack. 1 Blister packed in printed carton with packaging insert.

6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Registrant (Marketing Authorization Holder And Manufacturing Site Addresses)

7.1 Name and Address of Marketing Authorization Holder

GENERICS AND SPECIALITIES LTD.

31, AWONIYI ELEMO STREET,

OFF LATEEF SALAMI STREET.

AJAO ESTATE, LAGOS,

NIGERIA.

E-mail: info@zolonhealthcare.com

7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited

Trimul Estate, Khatraj, Taluka: Kalol,

District: Gandhinagar Gujarat, India.

Telephone no.: +91-02764-665000

Fax: +91-02764-281809

Email: info@lincolnpharma.com

Website: www.lincolnpharma.com

7.3 Marketing Authorization Number

To be included after obtaining first registration.

7.4 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

8. Date of Revision of the Text

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9. Dosimetry (If Applicable)

Not Applicable

10. Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable