1.3.1

Summary of Product Characteristics (SmPC)

1. Name of the medicinal Product

1.1 Name of the medicinal Product

Aceclofenac and Paracetamol Tablets

1.2 Strength

Each Film coated tablet contains:

Aceclofenac BP 100 mg

Paracetamol BP 325 mg

Excipients Q.S.

Colour: Titanium Dioxide BP

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

Aceclofenac BP and Paracetamol BP

2.2 Quantitative Declaration

Sr. No.	Ingredients	Specification	Standard Quantity (mg/Tablet)	Reason for Inclusion
	Mixing:			
01	Aceclofenac (A)	BP	100.00	Analgesic, Anti-inflammatory
02	Paracetamol	BP	325.00	Anti-Pyretic
03	Microcrystalline Cellulose (Plain) (C)*	BP	59.580	Diluent
04	Propylene Glycol	BP	2.00	Solubilizer
05	Povidone (PVPK-30)	BP	20.00	Binder
	Lubrication:			
06	Crosscarmellose Sodium	USP-NF	10.00	Disintegrant
07	Pregelatinized Starch (Starch 1500)	BP	25.00	Diluent
08	Colloidal Anhydrous Silica (Aerosil)	BP	10.00	Disintegrant
09	Microcrystalline Cellulose (pH 102)	BP	40.80	Diluent

10	Magnesium Stearate	BP	5.00	Lubricant
11	Purified Talc	BP	5.00	Lubricant
	Coating:			
12	Colour White SC-SP-3180 (Spraycel)	In-House	15.00	Colouring agent
13	Purified Water	BP	Q.S.	Solvent

3. Pharmaceutical Form

Film Coated Tablets.

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

4. Clinical Particulars

4.1 Therapeutic Indications

Aceclofenac with Paracetamol Tablet is indicated for:

Osteoarthritis

Rheumatoid arthritis

Ankylosing spondylitis

Pain

Inflammation

Acute musculoskeletal disorders and soft tissue inflammation such as periarthritis, sprains, strains, tenosynovitis,

bursitis, pain in fractures and dislocation.

Relief of pain and inflammation associated with orthopedic, dental, gynecological and other minor surgical procedures.

4.2 Posology and Method of Administration

Aceclofenac with Paracetamol Tablet is supplied for oral administration in adults.

The maximum recommended dose of Aceclofenac with Paracetamol Tablet is one tablet twice daily.

4.3 Contraindications

Aceclofenac with Paracetamol Tablet is contraindicated in the following situations:

Patients sensitive to Aceclofenac, Paracetamol or to any of the excipients of the product

Patients in whom aspirin or other NSAIDs, precipitate attacks of bronchospasm, acute rhinitis or urticaria or patients hypersensitive to these drugs

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

Patients with severe heart failure, hypertension, hepatic or renal insufficiency

Third trimester of pregnancy.

4.4 Special Warnings and Special Precautions for Use

Aceclofenac with Paracetamol Tablet may cause dizziness. Driving or operating machinery is to be avoided.

Individuals receiving long-term treatment should be regularly monitored for renal function tests, liver function tests and blood counts. It is to be used with caution in hepatic porphyria, coagulation disorders, history of peptic ulcers, ulcerative colitis, Crohn's disease, SLE, cerebrovascular bleeding, pregnancy and lactation. Caution should be exercised in patients with mild to moderate impairment of cardiac, hepatic or renal function and in elderly patients who are more likely to be suffering from these conditions. Caution is also required in patients on diuretic therapy or otherwise at risk of hypovolemia. As with other NSAIDs and combinations, caution is advised in elderly patients who are more likely to have concomitant renal, hepatic orcardiovascularimpaim1ent or receiving concurrent medication.

Pregnancy: The drug in not recommended in pregnant women.

Lactation: The drug in not recommended in breast-feeding women.

4.5 Interaction with other medicinal products and other forms of interaction

Drug interactions associated with Aceclofenac are similar to those observed with other NSAIDs. Aceclofenac may increase the plasma concentrations of lithium, digoxin and methotrexate. It may increase the activity of anticoagulants, inhibit the activity of diuretics, enhance cyclosporine nehrotoxicity and precipitate convulsions when co-administered with quinolone antibiotics. Co-administration of Aceclofenac with other NSAIDs and corticosteroids are to be avoided due to increased incidence of side-effects.

The risk of Paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce hepatic microsomal enzymes. Co-administration of Paracetamol with rifampicin, isoniazid, chloramphenicol, antiepileptic drugs and antiviral

drugs is to be avoided. Metoclopromide may increase the absorption of Paracetamol whereas excretion and plasma concentration may be altered when co-administered with probenecid. Cholestyramine also reduces the absorption of Paracetamol.

4.6 Fertility, Pregnancy and Lactation

Pregnancy: The drug in not recommended in pregnant women.

Lactation: The drug in not recommended in breast-feeding women.

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

Most of the adverse events are minor and reversible with treatment discontinuation.

Effects on gastrointestinal system: dyspepsia, abdominal pain and rise in hepatic enzymes.

Effects on skin: As with other NSAIDs, severe mucocutaneous skin reactions may also occur.

Other reactions: Other rare side-effects include dizziness, constipation, vomiting, ulcerative stomatitis, rash, demmtitis, headache, fatigue, allergic reactions, anemia, granulocytopenia, thrombocytopenia, neutropenia, oedema, palpitation, leg cramps, flushing, purpura, paraesthesia, tremors, gastrointestinal bleeding, gastrointestinal ulceration, pancreatitis, interstitial nephritis, depression, abnormal dreaming, somnolence, insomnia, vasculitis, hypoglycemia, rise in blood urea, serum creatinine and serum potassium.

4.9 Overdose

Overdosage may cause nausea, vomiting, pain abdomen, dizziness, somnolence, headache, sweating, pancreatitis, hepatic failure and acute renal failure.

Treatment, if required, includes gastric lavage, activated charcoal and other symptomatic measures as per medical advice.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Analgesic, Anti-inflammatory, Antipyretic

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. Paracetamol inhibits the synthesis of prostaglandins in the central nervous system and peripherally blocks pain impulse generation; also produces antipyresis effect from inhibition of hypothalamic heat-regulating center.

5.2 Pharmacokinetic Properties

Aceclofenac:

Absorption: Aceclofenac is well absorbed from gastrointestinal tract and peak plasma concentrations (Cmax) 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.

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 is approximately 4 hours.

Paracetamol:

Absorption: Paracetamol is rapidly and almost completely absorbed from gastrointestinal tract with peak plasma Concentrations (Cmax) occurring about! 0 to 60 minutes after oral administration.

Distribution: Plasma protein binding is negligible at usual therapeutic concentration but increases with increasing concentrations. It is relatively uniformly distributed throughout most body fluids. The plasma half life (t l/2) 2-3 hours and the effect after oral dose lasts for 3-5 hours.

Metabolism and Excretion: Paracetamol is metabolized predominantly in liver and excreted in the urine mainly as glucuronide and sulfate conjugate. Less than 5% is excreted unchanged.

5.3 Preclinical Safety Data

Not Applicable

6 Pharmaceutical Particulars

6.1 List of Excipients

Microcrystalline Cellulose (Plain) BP

Propylene Glycol BP

Povidone (PVPK-30) BP

Croscarmellose Sodium USP-NF

Pregelatinized Starch (Starch 1500) BP

Colloidal Anhydrous Silica (Aerosil) BP

Microcrystalline Cellulose (PH 102) BP

Purified Talc BP

Magnesium Stearate BP

Colour White SC-SP 3180 Spraycel IH

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

White to off-white coloured, capsule shaped, film coated tablets, plain on both side. 10 tablets are packed in Alu-Alu blister pack. 1 Blister packed in printed carton along 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.: +91-07949-135000

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