SUMMARY PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product:

ACLOSARA P (Aceclofenac and Paracetamol tablets)

2. Qualitative and Quantitative Composition:

Each film coated tablet contains:

Aceclofenac BP: 100 mg

Paracetamol BP: 500 mg

Excipients: q.s.

Colour: Sunset yellow & Titanium Dioxide

For a full list of Excipients see section 6.1

3. Pharmaceutical Form: Tablet

Light Orange colored, oblong, film coated tablets having a break line on one side and plain on other side.

4. Clinical Particulars:

4.1 Therapeutic indications:

Acecor P 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

One tablet twice daily or as directed by the Physician.

Tablet Should be taken as whole

Method of administration

For oral administration.

4.3 Contraindications

Acecor P 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 precautions for use

GI disease; renal or hepatic impairment; alcohol-dependent patients; asthma or allergic disorders; haemorrhagic disorders; hypertension; cardiac impairment Monitor renal and hepatic function and blood counts during long term treatment. Persistently elevated hepatic enzyme levels may require drug withdrawal. Pregnancy, lactation.

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 nephrotoxicity and precipitate convulsions when coadministered 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, anti-epileptic drugs and antiviral drugs is to be avoided. Metoclopramide 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 & use machines

Elderly, Caution when driving or operating machinery.

4.8 Undesirable Effects

Paracetamol: Nausea, allergic reactions, skin rashes, acute renal tubular necrosis.

Aceclofenac: Diarrhoea, headache, vertigo, dizzies, nervousness, tinnitus, depression, drowsiness, insomnia; fever, angioedema, bronchospasm, rashes; blood dyscrasias.

Potentially Fatal: Paracetamol: Very rare, blood dyscrasias (e.g., thrombocytopaenia, leukopenia, neutropenia, agranulocytosis); liver damage. Aceclofenac: Severe GI bleeding; nephrotoxicity.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions to the National Regulatory Agents.

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.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions to the National Regulatory Agents

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Non-Steroidal Anti Inflammatory

ATC code: Paracetamol - N02BE01, **Aceclofenac** – M01AB16

5.1 Pharmacodynamic Properties

Aceclofenac is a non-steroidal agent with marked anti-inflammatory and analgesic properties. The mode of action of aceclofenac is largely based on the inhibition to prostaglandin synthesis. Aceclofenac is a potent inhibitor of the enzyme cyclooxygenase, which is involved in the production of prostaglandins.

Paracetamol has analgesic and antipyretic properties, but it has no useful anti-inflammatory properties. Paracetamol's effects are thought to be related to inhibition of prostaglandin synthesis.

5.2 Pharmacokinetic Properties

After oral administration, Aceclofenac is rapidly and completely absorbed as unchanged drug. Peak plasma concentrations are reached approximately 1.25 to 3.00 hours following

ingestion. Aceclofenac penetrates into the synovial fluid, where the concentrations reach approximately 57% of those in plasma. The volume of distribution is approximately 25 L. The mean plasma elimination half-life is around 4 hours. Aceclofenac is highly protein-bound (>99%). Aceclofenac circulates mainly as unchanged drug. 4'- hydroxyaceclofenac is the main metabolite detected in plasma.

Absorption and Fate

Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1 to 4 hours. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdosage and cause liver damage.

Pharmacokinetics in Special populations:

Elderly: Approximately two- thirds of the administered dose is excreted via the urine, mainly as hydroxy metabolites. No changes in the pharmacokinetics of aceclofenac have been detected in the elderly.

5.3 Preclinical safety Data: None stated

6. Pharmaceutical Particulars:

6.1 List of excipients:

Sr. No.	Name of Excipients	Specification
1.	Maize starch	BP
2.	Povidone K-30	BP
3.	Methyl Paraben	BP
4.	Propyl Paraben	BP
5.	Sodium Metabisulphite	BP

6.	Purified Water	BP
7.	Ethyl cellulose 20 cps	BP
8.	Isopropyl alcohol	BP
9.	Dichloromethane	BP
10.	Magnesium stearate	BP
11.	Micro crystalline cellulose	BP
12.	Purified Talc	BP
13.	Hypromallose 15 cps	BP
14.	Titanium Dioxide	BP
15.	Sunset yellow lake	IH

6.2 Incompatibilities: Not applicable

6.3 Shelf life: 36 Months

6.4 Special precautions for storage:

Store below 30°C in dry place. Protect from light.

Keep medicine out of reach of children.

6.5 Nature and contents of container:

10 tablets are packed in Alu-Alu blister.

Such 3 blisters to be packed in a carton along with a pack insert.

6.6 Special Precaution for Disposal and other handling: Not applicable

6.7 Marketing authorization holder and manufacturing site addresses

Manufactured in India by:
Magbro Healthcare Pvt. Ltd
Located at village Mehsa Tibba,
P.O. Manjholi, The Nalagarh, Dist. Solan- 174101,
Himachal Pradesh, India.

Manufactured For & Marketed by:
KRISHNA CHEMISTS LTD.
P.O. BOX 3328-00506
NAIROBI, KENYA.

7. Marketing Authorization Number
CTD4509

8. Date of first authorization/renewal of the authorization

19/07/2026

9. Date of revision of the text

19/07/2026