1.6 Product Information

1.6.1 PRESCRIBING INFORMATION (SUMMARY OF PRODUCTS CHARACTERISTICS)

(SPC, CONTAINER LABELING & PATIENT INFORMATION LEAFLET, MOCK-UPS AND SPECIMENS)

SPC – Summary of the Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

FINACE - MR (Aceclofenac, Paracetamol and Chlorzoxazone Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Aceclofenac BP	100 mg
Paracetamol BP	500 mg
Chlorzoxazone USP	375 mg
Colour: Quinoline yellow	
Excipients	q.s

3. PHARMACEUTICAL FORM

Film-coated tablets.
A Yellow coloured, caplet shaped, biconvex, film coated tablet having plain on both sides.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

It is used in treatment of Osteoarthritis rheumatoid arthritis ankylosing spondylitis.

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4.2 Posology and method of administration

For adults: Aceclofenac 100 mg mixed paracetamol 500 mg and Chlorzoxazone USP 375 mg: Twice a day. Maximum: 2 tablets/day.

4.3 Contraindications

Contraindicated in patients with severe ulcer, gastrointestinal bleeding, and hypersensitivity.

4.4 Special warnings and precautions for use

Caution should be exercised in patients with history of Crohn's disease, bruising, heart, liver, or kidney disease, gastrointestinal disease, blood clotting problems, systemic lupus erythematosus, elderly, during pregnancy, alcohol-dependent patients, and breastfeeding. It may cause dizziness or drowsiness, do not drive a car or operate machinery while taking this medication.

Known to interact with other drugs like AliskirenAmprenavir Cimetidine HCl Colestipol HCl Cyclosporin a DigoxinErythromycin Mibefradil Di HCl Nicotinic Acid Repaglinide Warfarin Na.

4.5 Interaction with other medicinal products and other forms of interaction

Diuretics: Reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs. Although it was not shown to affect blood pressure control when co-administered with bendrofluazide, interactions with other diuretics cannot be ruled out. When concomitant administration with potassium-sparing diuretics is employed, serum potassium should be monitored.

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

Lithium: Decreased elimination of lithium.

Methotrexate: Decreased elimination of methotrexate. Caution should be exercised if NSAIDs and methotrexate are administered within 24 hours of each other, since NSAIDs may increase plasma levels, resulting in increased toxicity.

Ciclosporin: Increased risk of nephrotoxicity.

Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

Corticosteroids: Increased risk of gastrointestinal ulceration or bleeding.

Anti-coagulants: NSAIDs may enhance the effects of anti-coagulants, such as warfarin. Close monitoring of patients on combined anti-coagulants and Aceclofenac Tablets therapy should be undertaken.

Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with zidovudine. There is evidence of an increased risk of haemarthroses and haematoma in HIV(+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

Antidiabetic agents: Clinical studies have shown that diclofenac can be given together with oral antidiabetic agents without influencing their clinical effect. However, there have been isolated reports of hypoglycaemic and hyperglycaemic effects. Thus with Aceclofenac Tablets, consideration should be given to adjustment of the dosage of hypoglycaemic agents.

Other NSAIDs: Concomitant therapy with aspirin or other NSAIDs may increase the frequency of adverse reactions, including the risk of GI bleeding.

4.6 Pregnancy and lactation

Pregnancy D There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans but potential benefits may warrant use of the drug in pregnant women despite potential risks

Lactation L4 There is positive evidence of risk to a breastfed infant or to breastmilk production but the benefits of use in breastfeeding mothers may be acceptable despite the risk to the infant eg if the drug is needed in a lifethreatening situation or for a serious disease for which safer drugs cannot be used or are ineffective

4.7 Effects on ability to drive and use machines

No such effects.

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 (Eg, Thrombocytopaenia, Leucopaenia, Neutropaenia, Agranulocytosis); Liver Damage. Aceclofenac: Severe GI Bleeding; Nephrotoxicity.

4.9 Overdose

If the drug overdose happens' gastric lavage or enema is used to empty the stomach as soon as possible. Symptomatic treatment is started as per the need.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Aceclofenac : M01AB16
Paracetamol : N02BE01
Chlorzoxazone : M03BB03

Aceclofenac

NSAID, Analgesic, Antiinflammatory, Anti-arthritic.

Mechanism of Action of Aceclofenac

This drug has several mechanism of action.

1. It inhibits cyclooxygenase (COX) activity and to suppress the PGE2 production by inflammatory cells, by inhibiting IL-Beta & TNF in the inflammatory cells (Intracellular Action).
2. It blocks degeneration and stimulates synthesis of extra cellular matrix of cartilages by inhibiting the action of different cytokines.
3. Drug and its metabolites inhibit IL-6 production by human chondrocytes. This leads to inhibition of increase of inflammatory cells in synovial tissue, inhibition of IL-1 amplification, inhibition of increased MMP synthesis and thus ensuring proteoglycan production.
4. It inhibits IL-1 and TNF production by human chondrocytes, inflammatory cells and synovial cells and therefore blocks suppression of GAG and collagen synthesis and stimulates growth factors mediated synthesis of GAG and collagen.
5. 4`-hydroxyaceclofenac a metabolite of aceclofenac inhibits pro MMP1 and pro MMP3 produced by synovial cells (Rheumatoid Synovial Cells) in serum and in synovial fluid and thus inhibits progressive joint destruction by MMPs.
6. Aceclofenac inhibits Neutrophil Adhesion & Accumulation at the inflammatory site in the early phase and thus blocks the pro-inflammatory actions of Neutrophils.
7. Aceclofenac is also an NSAID with greater COX-2 specificity

Paracetamol

Acetanilide derivative, Non-narcotic Analgesic,Antipyretic.

Mechanism of Action of Paracetamol

Paracetamol has analgesic and antipyretic action.

It is more active on cyclo-oxygenase enzyme in brain. Peripherally it is a poor inhibitor of prostaglandin synthesis.

Analgesic action: Paracetamol raises the pain threshold and produces analgesic effect.

Antipyretic action: Paracetamol lowers fever by direct action on the thermoregulatory centre in the Hypothalamus and block the effects of endogenous pyrogen.

Chlorzoxazone

A benzoxazolone derivative, Centrally acting Muscle relaxant and mild sedative.

Mechanism of Action of Chlorzoxazone
This muscle relaxant works by blocking nerve impulses (or pain sensations) that are sent to your brain. It inhibits degranulation of mast cells, subsequently preventing the release of histamine and slow-reacting substance of anaphylaxis (SRS-A), mediators of type I allergic reactions. It may also reduce the release of inflammatory leukotrienes. Chlorzoxazone may act by inhibiting calcium influx.

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

Paracetamol
Absorption: Paracetamol is rapidly and completely absorbed after oral administration.
Distribution: It is distributed mostly in the body in unbound form.
Metabolism: It is extensively metabolised in the liver.
Excretion: Excreted in the urine.

Chlorzoxazone
Absorption- Rapidly and completely absorbed after oral administration.
Distribution- Widely distributed in the body.
Metabolism- It is metabolized in the liver to its metabolites by glucoronide conjugation.
Excretion- It is excreted through urine.

5.3 Preclinical safety data
Not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sr. No.	Ingredients	Specification
1.	Maize Starch	BP
2.	Sodium lauryl sulfate	BP
3.	Purified Water	BP
4.	Methyl Hydroxybenzoate	BP
5.	Propyl Hydroxybenzoate	BP
6.	Povidone.K-30	BP
7.	Purified Talc	BP
8.	Croscarmellose sodium	BP
9.	Colloidal Anhydrous Silica	BP
10.	Magnesium Stearate	BP
11.	Hypromellose	BP
12.	Purified Talc	BP
13.	Titanium Dioxide	BP
14.	Isopropyl Alcohol	BP
15.	Dichloromethane	BP
16.	Diethyl phthalate	BP
17.	Colour Quinoline Yellow	IHS

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30°C in dry place.

6.5 Nature and contents of container

10 Tablet in Blister & 2 such Blisters in a carton = 2 x 10 = 20 Tablet.

6.6 Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

Ochoa Laboratories

430, Mzz. F, Gundecha Indl. Complex

Akurli Road, kandivali (E).

Mumbai – 400101. India.

E-mail: support@aurochemgroup.com

8. MARKETING AUTHORISATION NUMBER(S)

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9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT