SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product

UNIACE TABLETS

2. Qualitative and Quantitative Composition

Each film coated tablet contains: Aceclofenac 100 mg
Paracetamol 500 mg
Excipients ..... q.s.

For excipients, see 6.1.

3. Pharmaceutical Form

Tablet for oral use.

4.Therapeutic indications

4.1 Clinical Particulars

Uniace 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

Posology
The recommended dose of Uniace 1 tablet twice daily.
Generally, no dose adjustment is necessary in elderly patients and those with mild renal impairment. Safety and efficacy has not been established in children.
Keep out of reach of children.

Method of administration For Oral use only

4.3 Contraindications

Uniace 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

Uniace may cause dizziness. Driving or operating machinery are 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.

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 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, anti-epileptic drugs andantiviral 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 Pregnancy and lactation

NSAIDs like Aceclofenac should not be used during pregnancy or labour unless the potential benefit to the patient outweighs the potential risk to the foetus.
In limited studies so far available, NSAIDs like aceclofenac can appear in breast milk in very low concentrations. Uniace should, if possible, be avoided when breastfeeding.

4.7 Effects on ability to drive and use machines

Uniace may cause dizziness. Driving or operating machineries are to be avoided.

4.8 Undesirable effects

Most of the adverse events are minor and reversible with treatment discontinuation. The majority of side effects are related to gastrointestinal system (dyspepsia, abdominal

pain, nausea and diarrhoea), most frequent being dyspepsia, abdominal pain and rise in hepatic enzymes. Other rare side-effects include dizziness, constipation, vomiting, ulcerative stomatitis, rash, dermatitis, headache, fatigue, allergic reactions, anaemia, 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. As with other NSAIDs, severe muco-cutaneous skin reactions may occur.

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 Pharmacodynamic properties

Pharmacotherapeutic group: Non-Steroidal Anti Inflammatory Drug ATC code:
Paracetamol - N02BE01

Aceclofenac – M01AB16
Aceclofenac relieves pain and inflammation through a variety of mechanisms and in addition exerts stimulatory effects on cartilage matrix synthesis.
Anti-inflammatory activity: The anti-inflammatory effects of Aceclofenac have been

shown in both acute and chronic inflammation. It inhibits various mediators of pain and inflammation including:
• PGE2 via cyclooxygenase inhibition (COX-1 & COX-2) after intracellular metabolism to 4’ hydroxy-aceclofenac and diclofenac in human rheumatoid synovial cells and other inflammatory cells.
• IL-1β, IL-6 and tumour necrosis factor in human osteoarthritic synovial cells and human articular chondrocytes.
• Reactive oxygen species (which plays a role in joint damage) has also been observed in patients with osteoarthritis of knee.
• Expression of cell adhesion molecules (which is implicated in cell migration and inflammation) has also been shown in human neutrophils.
Stimulatory effects on cartilage matrix synthesis: Aceclofenac stimulates glycosaminoglycan synthesis in human osteoarthritic cartilage by inhibition of IL-1β and suppresses cartilage degeneration by inhibiting IL-1β mediated promatrix metalloproteinase production and proteoglycan release. Paracetamol is a clinically proven analgesic and antipyretic agent with weak anti-inflammatory effect. Analgesic action: The central analgesic action of Paracetamol resembles that of aspirin. It produces analgesia by raising pain threshold. Antipyretic effect: The antipyretic effect of Paracetamol is attributed to its ability to inhibit COX in the brain where peroxide tone is low.

Recent evidence suggests inhibition of COX-3 (believed to be splice variant product of the COX-1 gene) could represent a primary central mechanism by which Paracetamol decreases pain and possibly fever.

5.2 Pharmacokinetic properties

Aceclofenac is well absorbed from gastrointestinal tract and peak plasma concentrations (Cmax) are reached 1-3 hours after an oral dose. 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 (Cmax or AUC). In patients with knee pain and synovial fluid effusion, the plasma concentration of Aceclofenac was twice that in synovial fluid after multiple doses of the drug. 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 is rapidly and almost completely absorbed from gastrointestinal tract with

peak plasma concentrations (Cmax) occurring about 10 to 60 minutes after oral administration. Plasma protein binding is negligible at usual therapeutic concentration but
Increases with increasing concentrations Acetaminophen s relatively uniformlydistributed throughout most body fluids. The plasma half-lifeafter oral dose lasts for 3-5 hours. 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

None

6. Pharmaceutical Particulars

6.1 List of excipient(s)

Maize Starch, Gelatin, Methyl Paraben, Propyl Paraben, Purified Talc, Magnesium Stearate, Sodium Starch Glycolate, Aerosil, Wincoat WT-01076 Orange, Isopropyl Alcohol, Dichloromethane.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30oc. Protect from light and moisture.

6.5 Nature and contents of container

Finished product is packed in blister pack of 10 Tablets. Such one blister is packed in a Carton along with product insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

Uniza Lifecare Private Limited -

Sr No 919 7 Old Sr No 404

Kadi Detroj Road Balasar Tal Kadi

Dist Mehsana Gujarat Pin 382715,

India

8. MARKETING AUTHORISATION NUMBER

FDA/SD.243-101849

9. DATE OF FIRST AUTHORIATION OR RENEWAL

08/10/2024

10. DATE OF REVISION OF THE TEXT

05/2025