ACEPAR-MR CAPLETS

Summary of product characteristics.

1. **Name of the medicinal product**. Acepar –MR Caplets
2. **Qualitative and quantitative composition**

Each Film coated caplet contains:

Aceclofenac BP 100 mg and Paracetamol BP 500 mg &Chlorzoxazone USP 375mg

3. **Pharmaceutical form**

White coloured caplet, with a break line on one side and plain on the other for oral administration.

4. **Clinical particulars**

4.1 Therapeutic indications

ACEPAR - MR caplets is indicated for relief of severe pain and inflammation in Osteoarthritis, Rheumatoid arthritis, Ankylosing spondylitis, Low back pain, Dental pain, Gynaecological pain and painful and inflammatory conditions of ear, nose & throat. It is also used in the symptomatic treatment of painful muscle spasm associated with musculoskeletal conditions.

Dosage and direction for use.

The recommended dose of ACEPAR –MR is 1 caplet 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.

4.3 Contra-indications.

Hypersensitivity, gastrointestinal bleeding, moderate to severe renal impairment and pregnancy

4.6 Pregnancy and lactation.

Aceclofenac and Chlorzoxazone are contraindicated during pregnancy and breastfeeding hence the combination cannot be used

4.7 Effects on ability to drive and use machines.

Avoid driving and operating machinery

4.8 Undesirable effects.

Nausea,allergic reactions,skin rashes, acute renal tubular necrosis,diarrhea,headache,vertigo, dizziness,nervousness,tinnitus,depression,drowsiness,insomnia,fever,angioedema,bronchospasm,rashes and blood dyscrasias

4.9 Overdose

Management of acute poisoning with NSAIDS essentially consists of supportive and symptomic measures

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group-Non-Steroidal anti-inflammatory, non-opiate analgesic, antipyretic and muscle relaxant drug category.

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:

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 litres. 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. Paracetamol is relatively uniformly distributed throughout most body fluids. The plasma half life (t1/2) 2-3 hours and the effect after 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.

Chlorzoxazone is reported to be completely absorbed after oral doses and peak plasma concentrations are achieved after 1 to 2 hours. It is rapidly metabolised in the liver via the cytochrome P450 isoenzyme CYP2E1, mainly to 6-hydroxychlorzoxazone, and excreted in the urine primarily as the glucuronide metabolite. The elimination half-life of Chlorzoxazone is about 1 hour.

5.3 Preclinical safety data.

Not applicable.

6. Pharmaceutical particulars.

6.1 List of excipients

Polyvinyl Pyrolidone (K30),Maize starch, Microcrystalline Cellulose, Sodium Starch glycollate, Magnesium Stearate, Purified talc, Hypromellose, Titanium dioxide, propylene glycol, Dichloromethane, Isopropyl alcohol and purified water

6.2 Incompatibilities

None known

6.3 Shelf life.

3 years from the date of manufacture.

6.4 Special precautions for storage:

Store in a cool dry place, below 30°C, from direct sunlight. Keep all medicines out of reach of children.

6.5 Nature and contents of container.

Alu-Alu blister packs of 1×10's in a unit box.

6.6 Special precautions for disposal and other handling

No special instructions

7. Marketing authorization holder.

Dawa limited,
Plot No: 7879/8, Baba Dogo road, Ruaraka,
P.o Box 16633-00620, Nairobi –Kenya.

8. Registration number(s)

Kenya registration number:H2007/453 Uganda registration number:3/14/8773
Malawi registrstion number:PMPB/PL12/80

9. Date of initial or renewed registration.

Initial date of registration (KENYA):28th February2007
Initial date of registration:(MALAWI):7TH February 2014
Initial date of registration(UGANDA):4TH April 2014

10. Date of revision of the text.

April 2017.