For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

TRUECEPROL

1. Generic Name

Oxaceprol Capsules.

2. Qualitative and quantitative Composition:

Each hard gelatin capsule contains:

Oxaceprol …….200mg

Excipients…….. q.s

Approved colours used in Capsule shell.

The list of excipients used are Maize starch, Microcrystalline Cellulose, Sodium Lauryl Sulphate, Povidone, Talc, Colloidal Silicon Dioxide, Croscarmellose Sodium and Magnesium Stearate.

3. Dosage form and strength

Dosage form: Hard gelatin capsule

Strength: 200 mg

4. Clinical particulars

4.1. Therapeutic indication

For the relief of sign and symptoms of osteoarthritis in adult patients.

4.2. Posology and method of administration

Oxaceprol hard gelatin capsule are preferably taken before a meal, unchewed, with sufficient liquid. The period of time for which the drug is to be administered depends on the character and intensity of the affection and is to be fixed individually.

Adult: 200 mg tid. In severe cases, initial dose can be increased to 400 mg tid. Taken before a meal, unchewed.

Elderly: Dose reduction is recommended..

4.3. Contraindications

- A known hypersensitivity to Oxaceprol or one of the other components.

4.4. Special warnings and precautions for use

Special precautions should be taken while use of oxaceprol in children, elderly, pregnancy and lactation.

4.5. Drugs interactions

Affects coagulation in patients under anticoagulative therapy with Vitamin K-antagonists. A control of the prothrombin time under simultaneous therapy with oxaceprol is, therefore, recommended.

It may decrease effects of anti-hypertensives and also affects toxicity of methotrexate and lithium..

4.6. Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy

Although up to now there are no indications that oxaceprol may have possible teratogenic effects, it is recommended not to use oxaceprol during a pregnancy.

Lactation

There does not exist any data on the placental transportation of Oxaceprol in humans or data on the transition into mother's milk.

Mutagenicity

Oxaceprol was extensively tested with regard to mutagenic properties. No indications of any mutagenic potential were found.

Carcinogenicity

There does not exist any tests on carcinogenicity; also bio-assays and clinical tests result did not showed any indications of a tumorigenic potential.

4.7. Effects on ability to drive and use machines

Unknown.

4.8. Undesirable effects

Under the treatment with Oxaceprol occasionally there have been observed gastrointestinal complaints, such as nausea, impaired appetite, pain in the stomach or diarrhea, which are often of a passing nature. Seldom there may occur allergic reactions (a reddening of the skin, an itching of the skin, exanthema). In exceptional cases the following reactions of allergic genesis were described: loss of hair, arthralgia, vasculitis, urticaria, giant urticaria and allergic eosinophilia.

Reporting of adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Report suspected adverse reactions via any point of contact available at www.torrentpharma.com or at email: pv@torrentpharma.com or call on 1800-120-3001

4.9. Overdose

Intoxications in humans have not occurred up to now and are actually hardly imaginable. In oral administration during bio-assays, only above the 500- to 1000-fold quantity of the standard dosage usual in the human field (10 mg/kg of body weight) toxic effects such as sedation, ptosis and piloerection could be observed.

5. Pharmacological properties

5.1. Mechanism of Action

The exact mechanism of action of oxaceprol is not known. It affects connective tissue metabolism and has been used in dermatology, to promote wound healing, and in rheumatic disorders. Experimental models of arthritis showed that oxaceprol reduced leukocyte extravasation, as well as the adhesion of leukocytes to capillaries. In vitro studies have shown that oxaceprol stimulates the uptake of 3H-glucosamine and 3H-proline in chondrocytes and the incorporation of 3H-proline in the macromolecular structure of the matrix of cartilage; which would be responsible for the activity on regenerating tissue.

5.2. Pharmacodynamic properties

Oxaceprol shows a distinct antiphlogistic 2nd analgesic efficacy. In preclinical studies the antiphlogistic efficacy has been tested with an excellent result in various models (carrageeninepaw edema, anaphylactic joint test, carrageenine-induced pleurisy, adjuvant-arthritis) and in comparison to reference antiphlogistics (indometacin, ASA, phenylbutazone, ibuprofen). These data have also been confirmed with a pyrexa erythema in the human model.

The analgesic efficacy has been shown by the Randall-Selitto and the Phenylquinone-Writhingtest. Clinically Oxaceprol has been tested in various indication fields of degenerative joint diseases. In placebo-controlled studies as well as double-blind and randomised studies against ibuprofen and dicfofenac the substance has been applied in the therapy of gon-, cox- and spondyl-arthrosis. While the cross-over test versus placebo showed the significant superiority of Oxaceprol, the substance is equal to ibuprofen and diclofenac in its symptomatic efficacy. In the therapy of rheumatoid arthritis Oxaceprol shows a tendency of superiority to diclofenac. In all indication fields the typical pain parameters (e.g. pain when stating to move, rest pain and pain following exercise), but also inflammation and flexibility parameters were distinctly improved.

5.3. Pharmacokinetic properties

Absorption

3.5 hours after oral application of oxaceprol there are maximal plasma levels. The bioavailability after oral administration amounts to about 30%.

Distribution

Due to its aqueous solubility, Oxaceprol is distributed in the whole organism. It permeates into the synovial liquid. No plasma-protein band has been proved. There are no indications of a cumulation.

Elimination

After IM or IV application the elimination half-time amounts to an average of 2 hours. The elimination occurs exclusively by renal way. The excretion is unchanged and complete. Oxaceprol is neither incorporated nor metabolised.

6. Nonclinical properties

6.1. Animal Toxicology or Pharmacology

Acute toxicity

When orally administered, the L&J in rats is 7.451 mg/kg of body weight, in mice 5-686 mg/kg of body weight: when IM-applied in rats and mice, respectively, it was more than 4,000 mg/kg and 2,921 mg/kg of body weight, respectively.

Chronic toxicity

The toxicity after repeated administration was determined in rats and beagles. For this purpose, the animals were given on 29 and 28 (resp.) successive days 3 dosages of the agent (4.5; 36; 288 mg/kg of body weight). In rats, apart from local effects caused by the application (inflammatory processes at the injection site) no unwanted effects occurred. In dogs, with the two lower dosages, no effects occurred. With the highest dosage, slight changes on cornea and renal tubules were observed, the pathological importance of which is not known. No cases of death occurred.

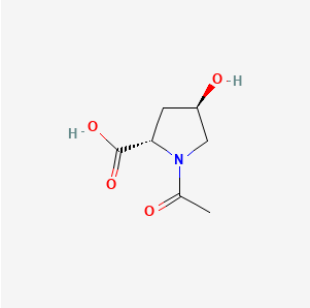
Reproduction

In rabbits, with the highest dosage of 288 mg/kg of body weight, teratogenic effects were observed which however, were not reproducible in a second identically conducted study.

7. Description

Oxaceprol

Oxaceprol is (2S,4R)-1-acetyl-4-hydroxypyrrolidine-2-carboxylic acid. The empirical formula is $C_7H_{11}NO_4$ and its molecular weight is 173.17 g/mol. The chemical structure of Oxaceprol is:



Trueceprol

Trueceprol is Size '2' hard gelatin capsule with green colour cap/white colour body containing white coloured granules.

The list of excipients used are Maize starch, Microcrystalline Cellulose, Sodium Lauryl Sulphate, Povidone, Talc, Colloidal Silicon Dioxide, Croscarmellose Sodium and Magnesium Stearate.

8. Pharmaceutical particulars

8.1. Incompatibilities

Not applicable

8.2. Shelf-life

Do not use later than the date of expiry.

8.3. Packaging information

Oxaceprol Capsules are available in the pack of 10 Capsules.

8.4. Storage and handing instructions

Store protected from light and moisture, at a temperature not exceeding 30°C.

Keep all medicines out of reach of children.

9. Patient Counselling Information

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies
- Have kidney or liver problems
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illness

- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

10. **Details of manufacturer**

    Ravenbhel Biotech

    EPIP, SIDCO, Kartholi,

    Bari-Brahmana, Jammu-181133

11. **Details of permission or licence number with date**

    Mfg. Lic No. is JK/01/11-12/192. Issue on 14.05.2015

12. **Date of revision**

    MAR-2026

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/TRUECEPROL 200mg/MAR 2026/03/PI