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

TRUECEPROL OD

1. Generic Name

Oxaceprol Sustained Release Tablets 600 mg.

2. Qualitative and quantitative Composition:

Each film coated sustained release tablet contains:

Oxaceprol…….600 mg

Colour: Titanium Dioxide I.P.

The excipients used are Mat SR Base-1, PVP K-30, Carbopol 71G, Magnesium Stearate, Colloidal Silicon Dioxide, Super Coat (Film), Talcum, Titanium Dioxide, Metolose 90SH, Microcrystalline Cellulose and Lactose..

3. Dosage form and strength

Dosage form: Film coated sustained release tablet

Strength: 600 mg

4. Clinical particulars

4.1. Therapeutic indication

For the treatment of pain associated with osteoarthritis in adult patients.

4.2. Posology and method of administration

Posology

The general recommended dose of the Oxaceprol SR Tablets 600 mg is one tablet once daily. Patients can safely use Oxaceprol SR Tablets 600 mg up to 42 days. Patient must consult the physician for further treatment with Oxaceprol SR Tablets 600 mg.

Method of administration

For oral use

Oxaceprol SR Tablets 600 mg should be taken before meals.

4.3. Contraindications

- Hypersensitivity to the active substance or to any of the excipients
- Pregnancy & Lactation
- Anticoagulant therapy with Vitamin K antagonists
- Hepatic impairment
- Renal impairment

4.4. Special warnings and precautions for use

Anticoagulant Therapy

Patients taking anticoagulants from the vitamin K antagonist group may not completely exclude the effect of Oxaceprol on blood coagulation. Therefore, when taking this medicine at the same time regular monitoring of prothrombin time is recommended.

Duration of the treatment

Patients can safely use Oxaceprol SR Tablets 600 mg up to 42 days. Patient must consult the physician for further treatment with Oxaceprol SR Tablets 600 mg.

Renal impairment

The safety and efficacy of Oxaceprol SR Tablets 600 mg in renal impairment patients has not been established.

Hepatic impairment

The safety and efficacy of Oxaceprol SR Tablets 600 mg in hepatic impairment patients has not been established

4.5. Drugs interactions

Patients taking anticoagulants from the vitamin K antagonist group may not completely exclude the effect of Oxaceprol on blood coagulation. Therefore, when taking Oxaceprol at the same time regular monitoring of prothrombin time is recommended.

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

Pregnancy

There are limited data on the use of Oxaceprol in pregnant women. So far no adverse effect has been observed.

Animal studies do not indicate direct or indirect teratogenic or embryo-fetotoxic effects of administration of Oxaceprol. The significance of these findings for human risk assessment is not clear. As a precaution, it is recommended to avoid using Oxaceprol during pregnancy and is justified exceptionally if the potential benefit to the mother far outweighs the potential risk to the foetus.

Breastfeeding

It is unknown whether Oxaceprol is excreted in human breast milk. Therefore, the use of Oxaceprol is not recommended during breastfeeding..

4.7. Effects on ability to drive and use machines

Oxaceprol has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

Clinical Trial Experience (unpublished data)

A total of 102 patients were evaluated for safety when treated with Oxaceprol SR Tablets 600 mg once daily. This includes all 102 patients treated for six weeks.

Treatment with Oxaceprol SR Tablets 600 mg once daily was well-tolerated.

The adverse events in Oxaceprol SR Tablets 600 mg once daily were abdominal pain (1.96%

- 2/102), nausea (1.96% - 2/102), diarrhea (0.98% - 1/102), dizziness (0.98% - 1/102) and itching in skin (1.96% - 2/102).

All adverse reactions were mild and transient in nature.

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.

4.9. Overdose

Oxaceprol exhibits very low toxicity. There is no specific antidote.

In animal studies, toxic effects of oral administration were observed only 500 to 1000 times higher doses than recommended doses for use in humans, i.e. at doses ≥10 mg / kg body weight (sedation, ptosis, piloerection).

5. Pharmacological properties

5.1. Mechanism of Action

Oxaceprol prevents leukocyte infiltration into the joints, thus inhibiting an early step of inflammatory cascade and presenting a novel class of anti-inflammatory agents.

5.2. Pharmacodynamic properties

Oxaceprol is an amino acid derivative and acts like analgesic and anti-inflammatory, which has been used for decades for the symptomatic treatment of degenerative and inflammatory joint disease in Europe3. Its anti-inflammatory and analgesic efficacy is comparable to the conventional non-steroidal anti-inflammatory drugs (NSAIDs) like Diclofenac, but has a different mode of action. Instead of inhibiting the synthesis of prostaglandins, Oxaceprol prevents leukocyte infiltration into the joints, thus inhibiting an early step of inflammatory cascade and presenting a novel class of anti-inflammatory agents.

Clinical studies (unpublished data)

A randomized, open label, active-controlled, multicentre, prospective, comparative, phase III clinical study was conducted on 204 patients aged 30 to 65 years clinically diagnosed with sign and symptoms of osteoarthritis of knee in India (only grade 1 to 3 according to Kellgren and Lawrence grading scale & VAS score 40 mm or above included). The study consists of two arms i.e., Oxaceprol SR Tablets 600 mg once daily and Oxaceprol Tablets 200 mg three times daily for 42 days of treatment.

Oxaceprol SR Tablets 600 mg once daily produces statistically significant improvement in Western Ontario and McMasters (WOMAC) individual osteoarthritis (OA) indices and Composite Index (for pain, stiffness and physical function) & Visual analog scale (VAS) from baseline to end of the study (Day 42) and the improvements between both the arms were non-significant and comparable. The results of the study were mentioned as below;

Treatment Arms	Improvement in WOMAC Score		Improvement in VAS Score	
	Mean Value at Baseline	Mean Value at Day 42	Mean Value at Baseline	Mean Value at Day 42
Oxaceprol SR Tablets 600 mg	62.45 (17.93)	36.23 (12.51)	7.27 (1.29)	4.80 (1.64)
Oxaceprol Tablets 200 mg	62.29 (17.27)	33.75 (11.88)	7.21 (1.14)	4.50 (1.48)
P Value	0.9493	0.1496	0.7048	0.1850

Mean (SD), VAS score represented in cms

5.3. Pharmacokinetic properties

Absorption

An oral bioavailability study of Oxaceprol SR Tablets 600 mg was conducted on 23 healthy adult human subjects under fasting conditions and the pharmacokinetic parameters were mentioned as below;

Pharmacokinetic Parameter	C_{max} (ng/mL)	AUC_{0-t} (ng.hr/mL)	$AUC_{0-\infty}$ (ng.hr/mL)	t_{max} (hr)	$t_{1/2}$ (hr)
Observations	1058.44±686.11	8771.81±3453.19	9145.76±3494.68	4.23±1.43	5.38±3.63

Mean±SD

An oral bioavailability study of Oxaceprol SR Tablets 600 mg was conducted on 21 healthy adult human subjects under fed conditions and the pharmacokinetic parameters were mentioned as below;

Pharmacokinetic Parameter	C_{max} (ng/mL)	AUC_{0-t} (ng.hr/mL)	$AUC_{0-\infty}$ (ng.hr/mL)	t_{max} (hr)	$t_{1/2}$ (hr)
Observations	876.97±270.60	8982.87±4006.10	9456.84±4189.53	5.07±1.16	5.81±3.38

Mean±SD

Distribution

Due to its aqueous solubility, Oxaceprol is distributed in the body. It permeates into the synovial fluid. No plasma-protein bond has been proved. There are no indications of accumulation.

Elimination

The elimination occurs exclusively by renal route.

6. Nonclinical properties

6.1. Animal Toxicology or Pharmacology

1.1 . **Acute toxicity**

When orally administered, the LD50 in rats is 7,751 mg/kg of body weight, in mice 5,688 mg/kg of body weight, when intra muscularly administered in rats and mice, it was more than 4,000 mg/kg and 2921 mg/kg of body weight respectively.

Chronic toxicity

The toxicity after repeated administration was determined in rats and beagles. The animals were given on 29 and 28 respectively 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 tub tiles were observed, the pathological importance of which is not known. No cases of death occurred.

Mutagenicity

Oxaceprol was extensively tested with regard to mutagenic properties. No incidence of mutagenic potential was found.

Carcinogenicity

No incidence of tumorigenic potential was found.

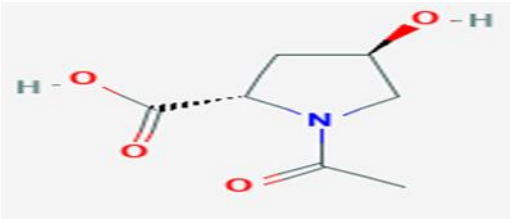
Reproductive toxicity

In a study conducted in pregnant female rabbits at a dose of 288 mg/kg/day, an increase was observed fetal resorption but the same effect was not observed in the repeated examination. Dose of 288 mg/kg/day in rabbits corresponds to a human dose 90 times the recommended therapeutic dose. In non-clinical trials, effects are observed only at dose exposures that are

significantly higher than the maximum allowed in humans, indicating their low relevance for clinical application.

7. Description

Oxaceprol is (2S,4R)-1-acetyl-4-hydroxypyrrolidine-2-carboxylic acid having molecular weight of 173.17 and molecular formula is C7H11NO4 and chemical structure is:



Oxaceprol Sustained Release Tablets are white coloured elongated, biconvex, film coated tablets, scored on one side. The excipients used are Mat SR Base-1, PVP K-30, Carbopol 71G, Magnesium Stearate, Colloidal Silicon Dioxide, Super Coat (Film), Talcum, Titanium Dioxide, Metolose 90SH, Microcrystalline Cellulose and Lactose.

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

TRUECEPROL OD is packed in strips of 10 tablets

8.4. Storage and handing instructions

Store below 30^{o} C, protected from light & moisture. 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

Synokem Pharmaceuticals Ltd.

Plot No. 56-57, Sector 6A,

I.I.E (SIDCUL),Ranipur (BHEL),

Hardiwar – 249403, Uttarakhand

11. Details of permission or licence number with date

Mfg Lic No. 27/UA/2018 issued on 28.11.2018

12. Date of revision

Feb 2026

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/ TRUECEPROL OD 600 mg/Feb 2026/03/PI