Ozenoxacin Lotion 2% w/w

LOSHUNOX™

Composition:
Ozenoxacin .....2% w/w
Absolute Alcohol I.P...5% w/w
Preservative:
Benzoic Acid IP ..... 0.1% w/w
In a Lotion base ..... q.s.

Therapeutic indication:
Ozenoxacin indicated for the treatment of superficial skin infections and acne (accompanied by purulent inflammation).

Ozenoxacin inhibits deoxyribonucleic acid (DNA) synthesis in bacteria by trapping gyrase-DNA and topoisomerase IV-DNA complexes involved in cell replication, resulting in apoptosis. Ozenoxacin shows a strong antibacterial effect against various aerobic/anaerobic, gram positive/gram negative bacteria, and high antibacterial activity against superficial skin infections from Staphylococcus aureus, Staphylococcus epidermidis and P. acnes.

Posology and method of administration
Posology
An appropriate amount of the drug should be applied to the affected area once daily. For facial acne, the drug should be applied to the affected area after washing the face.

Method of administration
In general, apply an adequate amount to the affected area once a day. For acne, apply to affected area after washing your face.
Strictly follow the instructions.

- Apply only to the skin. Do not use it to the eyes. If the medicine accidentally gets into the eyes, immediately flush the eyes with water.
- If you miss a dose, apply the missed dose as soon as you remember. You should not apply twice a day or apply two doses at one time.
- If you accidentally apply more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop applying this medicine unless your doctor instructs you to do so.

Contraindications
None

Special warnings and precautions for use

The most commonly reported adverse reactions include itching/dry skin/irritation at the applied site. If any of these symptoms occur, consult with your doctor or pharmacist.
The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

Before taking this medicine tell to your Doctor & pharmacist

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over the-counter medicines and dietary supplements as well as other prescription medicines.)

No pertinent entries.

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Effects on ability to drive and use machines
None

Use in special populations
Pregnancy
There are no available data on the use of Ozenoxacin in pregnant women to inform a drug associated risk. Systemic absorption of Ozenoxacin in humans is negligible following topical administration of Ozenoxacin. Due to the negligible systemic exposure, it is not expected that maternal use of Ozenoxacin will result in fetal exposure to the drug.

Animal reproduction studies were not conducted with Ozenoxacin. However, toxicity studies conducted in pregnant rats and rabbits administered the oral form of Ozenoxacin showed no significant adverse developmental effects (at >10,000 times the maximum human plasma concentration seen with dermal application of Ozenoxacin).

Breast-feeding
No data are available regarding the presence of Ozenoxacin in human milk, and the effects of Ozenoxacin on the breastfed infant or on milk production. However, breastfeeding is not expected to result in exposure of the child to Ozenoxacin due to the negligible systemic absorption of Ozenoxacin in humans following topical administration of Ozenoxacin. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Ozenoxacin and any potential adverse effects on the breast-fed child from Ozenoxacin or from the underlying maternal condition.

Overdose
Any sign or symptom of overdose, either topically or by accidental ingestion, should be treated symptomatically. No specific antidote is known.

Pharmacological properties
Pharmacodynamics properties
Exposure-Response Relationship
The exposure response relationship for Ozenoxacin following topical application has not been studied, however; a relationship is unlikely because systemic exposure following topical application is negligible.

Pharmacokinetic properties
Absorption
Four pharmacokinetic studies were conducted in 110 patients utilizing varying strengths of Ozenoxacin, up to 2%. Three of these studies assessed systemic absorption in healthy subjects and in subjects with impetigo. These studies were conducted with either single or repeated application of up to 1 g .

Distribution
Plasma protein binding of [^{14}C]- Ozenoxacin was moderate (~80 to 85%) and did not appear to be dependent on concentration. Since negligible systemic absorption was observed in clinical studies, tissue distribution has not been investigated in humans.

Elimination
Metabolism: Ozenoxacin was not metabolized in the presence of fresh human skin discs and was minimally metabolized in human hepatocytes.

Excretion: Studies have not been investigated in humans due to the negligible systemic absorption observed in clinical studies.

Microbiology

Mechanism of Action

Ozenoxacin inhibits deoxyribonucleic acid (DNA) synthesis in bacteria by trapping gyrase-DNA and topoisomerase IV-DNA complexes involved in cell replication, resulting in apoptosis. Ozenoxacin shows a strong antibacterial effect against various aerobic/anaerobic, gram positive/gram negative bacteria, and high antibacterial activity against superficial skin infections from Staphylococcus aureus, Staphylococcus epidermidis and P. acnes.

Resistance

The mechanism of quinolone resistance can arise through mutations of one or more of the genes that encode DNA gyrase or topoisomerase IV. Resistant organisms will typically carry a combination of mutations within *gyrA* and *parC* subunits.

Overall the frequency of resistant mutants selected by Ozenoxacin is $\leq 10^{-10}$

Interaction with Other Antimicrobials

Ozenoxacin has been tested in combination with 17 other commonly used antimicrobial agents against *S. aureus* and *S.pyogenes*. Antagonism interactions with Ozenoxacin were observed with ciprofloxacin against *S. aureus*.

Antimicrobial Activity

Ozenoxacin has been shown to be active against most isolates of the following microorganisms, both *in vitro* and in clinical infections.

Nonclinical properties

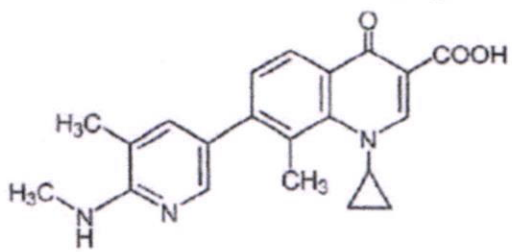
Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals to evaluate carcinogenic potential have not been conducted with Ozenoxacin.
Ozenoxacin demonstrated no genotoxicity when evaluated *in vitro* for gene mutation and/or chromosomal effects in the Ames test, mouse lymphoma cell assay, or when evaluated *in vivo* in a rat micronucleus test with demonstrated systemic exposure.
Oral doses of Ozenoxacin did not affect mating and fertility in male and female rats treated up to 500 mg/kg/day

Description

The chemical name of Ozenoxacin is 1-Cyclopropyl-8-methyl-7-(5-methyl-6-methylamino-pyridin-3-yl)-4-oxo1,4-dihydro-quinoline-3-carboxylic acid. Ozenoxacin as available in form of lotion, white to pale-yellow Colour viscous Liquid.

Ozenoxacin, has a molecular formula of $C_{21}H_{21}N_3O_3$, and a molecular weight of 363.41. The chemical structure is:



Pharmaceutical particulars

Incompatibilities

None

Shelf life

24 months

Packaging information

10 g Lotion Bottles

Storage and handing instructions

Store at a temperature not exceeding 25°C. Protect from light. Do not freeze.