For the use of a Medical Specialist only

1. GENERIC & BRAND NAME:

Ozenoxacin Lotion 2 % w/v
OZEWID™ LOTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Composition:
Ozenoxacin …..…….. 2 % w/v
Preservative:
Benzoic Acid I.P.…… 0.1% w/v
In a lotion base ……. q.s.

3. DOSAGE FORM AND STRENGTH

Refer section 1 & 2

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Ozenoxacin lotion is indicated for the treatment of Superficial skin infections and acne

4.2 Posology and method of administration

Apply appropriate amount of this medicine once in a day to affected part. For acne, apply on affected part after washing face.

4.3 Contraindications

It is contraindicated with patients having a hypersensitivity to the drug product.

4.4 Special warnings and precautions for use

As treatment of superficial skin infection, if the effect is not seen by using for a week, then use of this medicine should be discontinued.
As treatment of acne, if the effect is not seen by using for 4 weeks, then this medicine should be discontinued.
Further, if inflammatory rash has disappeared then it should not be used continuously.
When using this medicine, in order to prevent development of resistant bacteria, use should be for minimum period required for treatment of illness.

Potential for Microbial Overgrowth

The prolonged use of ozenoxacin lotion may result in overgrowth of non-susceptible bacteria and fungi. If such infections occur during therapy, discontinue use and institute appropriate supportive measures.

4.5 Drug Interactions

No studies on the interaction with other medicinal products & other forms of interaction have been performed.

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

Pregnancy

It is desirable not to use this lotion for pregnant women or to women having possibility of being pregnant.[Safety related to use for pregnant women is not established.]

Lactation

It is desirable not to use for nursing mothers. However, breast feeding should be avoided in case of unavoidable use of this lotion. [When ozenoxacin was administered subcutaneously in rats, migration in breast milk was seen.]

Pediatric Use

Safety of use in children with low birth weight, newborn, infants, children or children under 13 years of age is not established. (No experience of use.)

Geriatric Use
Clinical studies of Ozenoxacin did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

4.7 Effects on ability to drive and use machines
No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

As per Innovator's data from Japan, among 757 cases 35 cases (4.6%) showed side effects in clinical tests. Major side effects were itching of the part where this medicine was applied 8 cases (1.1%), drying of application site 8 cases (1.1%), and irritating sensation at application site 7 cases (0.9%).

	More than 1%	Less than 1%
Skin	Itching, dryness	Irritating sensation, scaling, desquamation, redness, uncomfortable feeling, dryness of skin, sensation of warmth.
Other		Rise in serum bilirubin, rise in AST (GOT), ALT(GPT), γ-GTP, rise in eosinophils.

4.9 Overdose
No overdose of Ozenoxacin was reported in clinical studies. Patients should be managed by symptomatic either by topical or accidental ingestion.

5. PHARMACOLOGICAL PROPERTIES
5.1 Mechanism of Action

Mechanism of Action
Ozenoxacin is a quinolone antimicrobial drug. The mechanism of action involves the inhibition of bacterial DNA replication enzymes, DNA gyrase A and topoisomerase IV. Ozenoxacin has been shown to be bactericidal against *S. aureus, S. pyogenes, S. 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 micro organisms, both in vitro and in clinical infections: Gram-positive bacteria *Staphylococcus aureus* (including methicillin-resistant isolates), *Streptococcus pyogenes, Staphylococcus epidermidis*, and *Propionibacterium acnes.*

5.2 Pharmacodynamic 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.

5.3 Pharmakokinetic properties

As per Innovator's data from Japan, When 10gm of this medicine was applied on back of healthy adults (8 cases) maximum concentration of Ozenoxacin in blood plasma was average 89.6pg/ml, excretion rate of Ozenoxacin and it's metabolites in urine was 0.0135%. When 5gm of this lotion was applied to back of healthy adults (8cases) 2 times a day for 7 days (total 13 times) multiple application, maximum concentration of Ozenoxacin in blood plasma was average 28.6pg/ml and excretion rate of Ozenoxacin and it's metabolites in urine was 0.00217%.

When this lotion was applied once a day for 4 weeks to whole face of common acne patients, concentration of this medicine in pustula throughout application period was 0.5778- 343.8µg/gm. Further, blood plasma concentration of Ozenoxacin detected at that time was 31.90 to 2189pg/ml.

In *in vitro* tests, Ozenoxacin was mainly metabolized by CYP3A4.

After subcutaneous administration of Ozenoxacin in rat and intravenous administration in dogs excretion after systemic circulation transition was mainly in feces.

6. NON CLINICAL PROPERTIES

6.1 Animal Toxicology or Pharmacology

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.

7. DESCRIPTION

OZEWID LOTION is supplied for external application, as a lotion dosage form. Each pack of OZEWID LOTION contains Ozenoxacin 2% w/v.

8. PHARMACEUTICAL PARTICULARS.

8.1 Incompatibilities

Not applicable

8.2 Shelf life

Refer pack

8.3 Packaging information

Refer pack

8.4 Storage and handling instructions

Refer pack

9. PATIENT COUNSELLING INFORMATION

Ozenoxacin is an Antimicrobial drug indicated for superficial skin infections, acne (accompanying purulent inflammation).

Apply appropriate amount of this medicine once in a day to affected part. Further, for acne apply on affected part after washing face.

Use Ozenoxacin lotion as directed by the healthcare practitioner. As with any topical medication, patients and caregivers should wash their hands after application if the hands are not the area for treatment.

Ozenoxacin lotion is for external use only. Do not swallow Ozenoxacin lotion or use it in the eyes, on the mouth or lips, inside the nose, or inside the female genital area.

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Revised Version No. 1.0, dated 07th June 2023

Use the medication for the entire time recommended by the healthcare practitioner, even though symptoms may have improved.
As treatment of superficial skin infection, notify the healthcare practitioner if there is no improvement in symptoms within a week after starting use of Ozenoxacin lotion.
As treatment of acne, notify the healthcare practitioner if there is no improvement in symptoms within 4 weeks after starting use of Ozenoxacin lotion.
Further, if inflammatory rash has disappeared then it should not be used continuously.
Do not use Ozenoxacin lotion if patient is allergic to the drug.

10. DETAILS OF MANUFACTURER
Refer Pack for manufacturer details.

Marketed by:
Abbott Healthcare Pvt. Ltd.
Angel Space, Bldg. D-4, Gala No. 1 to 6 &
11 to 16 Ground Floor, 101 to 106 &
111 to 116 First Floor, 201 to 206 & 211 to 216
2nd Floor, Pimplas, Dist. Thane, Bhiwandi - 421 302, India.

11. DETAILS OF PERMISSION OR LICENCE NUMBER
Refer Pack for Permission/License details

12. DATE OF REVISION
Version No. 2.0, dated 21st February 2024

For Product Complaints/Adverse events or Queries please write to **webmasterindia@abbott.com**