WOCKHARDT

Nadifloxacin 1% Cream

NADOXIN™ Cream

COMPOSITION:
Each gram contains

Active Ingredient:

Nadifloxacin	10 mg
In a cream base	q.s.

Inactive Ingredients:
Liquid Paraffin (Heavy), Cetosteryl alcohol, Alpha tocopherol, Propylene Glycol, Disodium Edetate, Cetomacrogol 1000, Sodium Hydroxide, Diethanolamine, Purified Water

DESCRIPTION:
Nadoxin™ (Nadifloxacin Cream) is a synthetic quinolone with potent broad-spectrum antibacterial activity.
Nadifloxacin Cream is intended for the treatment of acne vulgaris caused by Propionibacterium acnes and Staphylococcus spp. Prominent efficacy, low potential in inducing resistance in microorganisms, and high antibacterial activity against drug-resistant microorganisms have been well documented in extensive clinical studies.

PHARMACOLOGY:

1. **Antibacterial Spectrum:**
   In vitro, nadifloxacin showed a potent and broad spectrum antibacterial activity against aerobic Gram-positive, Gram-negative and anaerobic bacteria, including Propionibacterium acnes and Staphylococcus epidermidis. The drug activity is bactericidal. Nadifloxacin showed potent antibacterial activity against methicillin resistant Staphylococcus aureus (MRSA) that was similar to the potency against methicillin-sensitive Staphylococcus aureus (MSSA). The drug was also active against new quinolone-resistant MRSA. Nadifloxacin was not cross-resistant with other new quinolones.
2. **Mechanism of Action:**
   Nadifloxacin inhibits the enzyme DNA gyrase that is involved in bacterial DNA synthesis and replication, thus inhibiting the bacterial multiplication.
3. **Pharmacokinetics:**
   Following a single topical application of 10gm Nadifloxacin 1% cream to normal human back skin, the highest plasma concentration was determined to be 1.7 ng/ml with an elimination half-life of 19.4 hours. Approximately 0.09% of the administered dose was excreted in the urine over 48 hours post-dosing. The plasma concentration reached a steady state on Day 5 of the repeated administration study when Nadifloxacin 1% cream was applied at 5g twice daily to normal healthy individuals for a period of 7 days. The plasma concentration reached a peak of 4.1ng/ml at 8 hours post-final dosing with an elimination half-life of 23.2- hours. The urinary excretion rate reached 0.16% on Day 7.

INDICATIONS:
Treatment of acne vulgaris (patients with multiple inflamed lesions), folliculitis and other treatment of superficial topical bacterial infections caused by susceptible bacteria.

DOSAGE AND ADMINISTRATION:
Nadoxin™ cream should be applied to the lesions twice daily. However, in case of acne, it should be applied after washing the face.

CONTRAINDICATIONS:
Known hypersensitivity to nadifloxacin or any of the ingredients of the cream.

PRECAUTIONS:
As a rule, susceptibility testings should be performed prior to actual use of this drug to estimate nadifloxacin susceptibility. To minimise the chance that resistant microorganisms will develop as a result of therapy, the treatment duration should be the shortest feasible.

1. **General Precautions:**
   This drug should be discontinued if the desired therapeutic effect is not achieved at the recommended dose.
2. **Adverse Reactions:**
   Pruritis, irritation, redness, flushes, papules, feeling of facial warmth, increased sweating, contact dermatitis, dryness of the skin, and hot flushes may infrequently occur.
3. **Use during pregnancy:**
   The safety of this drug for use during pregnancy has not been established. (Clinical experience in pregnant women is insufficient)
4. **Use in Premature Babies, New-borns, and Infants:**
   The safety of this drug in premature babies, new-borns, and infants has not been established (the drug has not been studied in these patients)
5. **Caution in use:**
   This drug is intended for topical (dermal) application only and is not intended for ophthalmologic use. The drug should not be applied to the cornea or conjunctiva.
6. **Other:**
   Photosensitivity has been reported in patients taking synthetic quinolone antibacterial agents.

DRUG INTERACTIONS:
As the drug is topically applied and systemic absorption is low, the risk of clinically significant interaction is small. There are no reported drug interactions.

UNDESIRABLE EFFECTS:
Pruritis, irritation, redness, flushes, papules, feeling of facial warmth, increased sweating, contact dermatitis, dryness of skin, and hot flushes may may infrequently occur.

OVERDOSE:
Overdosage is unlikely with Nadifloxacin. In the event of accidental ingestion, general therapeutic measures normally adopted to treat poisoning with quinolone should be used..

STORAGE: Store below 30°C. Protect from light & moisture.

PRESENTATION: **Nadoxin™** cream is available in 10g and 20g tube.

Manufactured by:
WOCKHARDT LIMITED
Mumbai, India.

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THIS IS A MEDICAMENT

Medicament is a product, which affects your health, and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription, without consulting your Doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.