Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
NAXACOR CREAM
Nadifloxacin Cream 1%

2. Qualitative and quantitative composition
Each gm contains:
Nadifloxacin……10mg
For full list of excipients, see section 6.1

3. Pharmaceutical form
Cream for Topical use.
A white colour smooth cream.

4. Clinical particulars

4.1 Therapeutic indications
Treatment of acne vulgaris
Treatment of bacterial skin infections

4.2 Posology and method of administration
Adults (including elderly) and Paediatric population:
Nadifloxacin
cream 1% should be applied to the lesions twice daily.
In case of acne, it should be applied after washing the face.

4.3 Contraindications
Contraindicated in known hypersensitivity to Nadifloxacin or any excipient of the product.

4.4 Special warnings and precautions for use
A rule, susceptibility testing should be performed prior to the actual use of this drug to estimate Nadifloxacin susceptibility. To minimize the chance that resistant microorganisms will develop as a result of therapy, the treatment duration should be the shortest feasible. 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. This drug should be discontinued if the desired therapeutic effect is not achieved at the recommended dose.
Photosensitivity reactions have been known to develop under therapy with other quinolones administered systemically. While several studies in animals and man have shown neither phototoxic nor photoallergic potentials for the active ingredient Nadifloxacin, the cream base may have an enhancing effect on photosensitivity. Moreover, no experience is available on prolonged exposure to sunlight or artificial UV light under Nadifloxacin. Patients using Nadifloxacin cream should therefore avoid exposure to artificial UV irradiation (UV lamps, sun bed, solarium) as a matter of principle and exposure to sunlight whenever possible.

If hypersensitivity reactions (manifesting as itching, erythema, papules, vesicles) or severe irritation occurs, use of medication should be discontinued. The product should not be applied to broken skin (cuts and abrasions). There is no data covering the safety of concomitant treatment with other acne medications (e.g. benzoyl peroxide), and Nadifloxacin cream should therefore be used as a monotherapeutic only.
Nadifloxacin cream contains: Cetostearyl Alcohol, which may cause local skin reactions (e.g. contact dermatitis).
Pregnancy: The safety of this drug for use during pregnancy has not been established (clinical experience in pregnant women is insufficient).
Paediatric Use: The safety of this drug in children younger than 14 years has not been studied or established.

4.5 Interaction with other medicinal products and other forms of interaction

Absorption of Nadifloxacin after application of Nadifloxacin cream to the human skin is very low and therefore interaction with systemic medication given concurrently is unlikely. There is no evidence to indicate that the efficacy of systemically administered drugs is influenced by the topical use of Nadifloxacin cream. Nadifloxacin cream may cause skin irritation and therefore it is possible that the concomitant use of peeling agents, astringents, or products containing irritating substances such as aromatic and alcoholic agents may result in increased skin irritation.

4.6 Pregnancy and Lactation

For Nadifloxacin cream, no clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal, foetal development, parturition or postnatal development.
Caution should be exercised when prescribing to pregnant women.
Nadifloxacin is known to be excreted in milk and therefore Nadifloxacin Cream should not be used during lactation.
Under no circumstances must breast-feeding women apply Nadifloxacin on their chest.
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.)
Caution in use: This drug is intended for Topical (Dermal) application only and is not intended for ophthalmologic use. The drug should be applied to the cornea or conjunctive.

Other: photosensitivity has been reported in patients taking synthetic quinolone antibacterial agents.

4.7 Effects on ability to drive and use machines

Neither the pharmacodynamic profile nor clinical experience suggest any effect on the ability to drive or use machines.

4.8 Undesirable effects

Mild and transient side effects like itching and erythema may occur at the site of application.

Other side effects like flushes, papules, feeling of facial warmth, increased sweating, contact dermatitis, and dryness of the skin may infrequently occur.

These local side effects are very rare and occur in less than 5% of the patients.

4.9 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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Nadifloxacin is a synthetic quinolone with potent broad-spectrum antibacterial activity. It is bactericidal in nature. Nadifloxacin inhibits the enzyme DNA gyrase that is involved in bacterial DNA synthesis and replication, thus inhibiting bacterial multiplication. In vitro studies of Nadifloxacin showed potent and broad-spectrum antibacterial activity against aerobic Gram-positive, Gram-negative and anaerobic bacteria, including Propionibacterium acnes and Staphylococcus epidermidis. Nadifloxacin showed potent antibacterial activity against methicillin-resistant Staphylococcus aureus (MRSA), which was similar to potency against methicillin-sensitive Staphylococcus aureus (MSSA). The drug was also active against quinolone-resistant MRSA. Nadifloxacin does not show cross-resistance with other quinolones.

5.2 Pharmacokinetic properties

Following a single topical application of 10 gm Nadifloxacin 1% cream/gel 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/gel was applied in the dose of 5 g twice daily to normal healthy individuals for a period of 7 days. The plasma concentration reached a peak of 4.1 ng/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.

5.3 Preclinical safety data

No evidence of Nadifloxacin-induced mutagenesis was seen in a reverse mutation assay with bacterial systems and gene mutation and chromosomal aberration assays with cultured Chinese hamster cells. A chromosome aberration assay was positive with cultured human peripheral blood lymphocytes, but an in vivo micronucleus assay was

negative in mice. S(-)-Nadifloxacin was positive in both chromosomal aberration and micronucleus assays. Other new quinolones have been reported to be clastogenic.

6. Pharmaceutical Particulars

6.1 List of Excipients

Methyl Hydroxybenzoate BP
Cetomacrogol
Emulsifying wax
(Hydol 20) BP
Cetosteryl
Alcohol BP
White soft Paraffin BP
Light Liquid
Paraffin BP
Propylene
Glycol BP
Propyl Hydroxybenzoate BP

6.2 Incompatibilities

Not known

6.3 Shelf-Life

24 months

6.4 Special Precautions for storage

Store below 30°C. Protect from light.
Do not freeze.

6.5 Nature and Content of container

Primary Packing:10gm bulk filled in each Lami Tubes
Secondary Packing: Such 1 tube to be packed in a carton along with a pack insert.

6.6 Special precautions for disposal and other handling

Keep medicine out of reach of children. Replace cap after use.

7. Marketing Authorization Holder

Signature Healthcare Limited
Address:
Cape Business Park, Along Thika Super Highway, P. O. Box 66172-00800, Nairobi
Fax: +254-20-2555811, +254-705617118/0787617118

8. Marketing Authorization Number

H2025/CTD11574/21286

9. Date of first authorization/renewal of the authorization

8/10/2025

10. Date of revision of the text

8/10/2025