

# Nadif<sup>®</sup>

(Nadifloxacin)

Cream 10mg/g

1% W/W

نیڈیف ۱۰ ملی گرام / گرام کریم

(نیڈی فلوکسائین)

For External Use Only

صرف بیرونی استعمال کے لئے

## QUALITATIVE AND QUANTITATIVE COMPOSITION

Nadif<sup>®</sup> Cream 10mg/g

Each gram contains:

Nadifloxacin....10mg

Innovator's Specifications

## DESCRIPTION

Nadif<sup>®</sup> Cream is a topical fluoroquinolone antibiotic used to treat acne vulgaris and other skin infections with susceptible bacteria. It works by inhibiting the enzyme DNA gyrase to prevent bacterial multiplication.

## CLINICAL PHARMACOLOGY

### Mechanism of Action:

Nadifloxacin inhibits the enzyme DNA gyrase that is involved in bacterial DNA synthesis and replication, thus inhibiting the bacterial multiplication. Nadifloxacin in addition to determine a therapeutic antibacterial action, can have a sebostatic and anti-inflammatory action, thus contributing to the improvement of the clinical condition of the patient.

### Pharmacokinetics:

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.

### Pharmacodynamics:

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.

## **INDICATIONS AND USAGE**

Treatment of acne vulgaris and bacterial skin infections.

## **CONTRAINDICATIONS**

Tuberculous or syphilitic processes in the area to be treated; virus diseases (e.g. varicella, herpes zoster), rosacea, perioral dermatitis and post-vaccination skin reactions in the area to be treated. Hypersensitivity to the active substances or to any of the excipients. In general, Isocort should be used without occlusion.

## **INTERACTIONS**

Nadifloxacin is contraindicated in those patients with a history of hypersensitivity reactions to any of its components.

## **USE IN SPECIFIC POPULATION**

### **Pregnancy:**

The safety of this drug for use during pregnancy has not been established (clinical experience in pregnant women is insufficient).

### **Breast-feeding:**

Nadifloxacin should not be used during breast-feeding. It should not be applied to the breast area during lactation.

### **Paedriatic Use:**

The safety of this drug in children younger than 14 years has not been studied or established.

## **PRECAUTIONS**

Nadifloxacin should not be applied to skin that is broken or severely damaged. Do not use this medication if you are allergic to nadifloxacin or if you have had a bad reaction to similar treatments in the past. You are also recommended to consult your doctor before beginning use to make sure you do not have any health conditions that may cause unexpected complications during treatment. Nadifloxacin may not be safe or suitable for all patients. Always ensure your doctor is informed if you are pregnant or breastfeeding, using any other type of medication (including non-prescription medicine, vitamins, and supplements), as well as if you have any allergies, other illnesses, or pre-existing medication conditions.

Nadifloxacin contains cetyl alcohol, stearyl alcohol and cetostearyl alcohol which may lead to local skin reactions (e.g. contact dermatitis; a skin disease that occurs with contacting). This medicinal product contains methyl paraben (E218) which may cause allergic reactions which can possibly be delayed.

## **ADVERSE REACTIONS**

During the treatment with Nadifloxacin some patients may develop some adverse effects predominantly of the skin and subcutaneous tissue: burning and itching (in absolute the most common side effect), contact dermatitis, dryness and skin irritation.

## **DOSAGE AND ADMINISTRATION**

Nadifloxacin should be applied to the lesions twice daily. In case of acne, it should be applied after washing the face. Strictly use Nadifloxacin according to your doctor's instructions to get the safest and most effective results from treatment. Safe, suitable, and optimum dosage can vary and is dependent on the patient's health and medical history, as well as the condition you are treating.

To administer Nadifloxacin rinse and dry the area to remove any dirt or

loose skin, apply a small amount of cream, gently massage it into the skin, and leave the area uncovered to allow any excess medication to evaporate. Thoroughly wash your hands following each use to prevent any cream from contacting the mucous membranes or other areas of the skin not being treated.

## OVERDOSAGE

Results from acute toxicity studies do not indicate that any risk of acute intoxication is to be expected following a single dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion.

## INSTRUCTIONS

Dosage as directed by the physician.

Store below 30°C.

Protect from heat and light.

Keep all medicines out of the reach of children.

## PRESENTATION

Nadif® Cream 10mg is available in Tube.

ہدایات / طریقہ استعمال: خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔  
۳۰ ڈگری سینٹی گریڈ سے کم پر رکھیں۔ روشنی اور گرمی سے محفوظ رکھیں۔  
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

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ISO 9001:2015



ISO 14001:2015



ISO 45001:2018

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