Nadixa 1% cream

Nadifloxacin 1%

Pharmacological properties

Nadifloxacin is an antimicrobial drug for the topical treatment of defined forms of acne. Code ATC: D10 AF Nadifloxacin is a synthetic bactericidal quinolone with a broad spectrum of antibacterial activity against aerobic Gram-positive, aerobic Gram-negative and anaerobic bacteria, including Propionibacterium acnes and Staphylococcus epidermidis. Nadifloxacin has shown a high antibacterial activity against methicillin-resistant Staphylococcus aureus (MRSA), with similar strength to methicillin sensitive Staphylococcus aureus (MSSA). It is also effective against recently emerged MRSA quinolone-resistant. The bactericidal action of Nadifloxacin results from the inhibition of the DNA gyrase (topoisomerase II) and topoisomerase IV bacterial enzymes. These enzymes are essential for the replication, transcription and repair of bacterial DNA. The metabolism is produced by oxidation and conjugation processes. No cross-resistances of Nadifloxacin to other new quinolones have been observed.

Composition

1 g of cream contents 10 mg of Nadifloxacin. Excipients, q.s. 100 g of cream contents 1 g of Nadifloxacin. Excipients q.s.

Indications

Topical treatment of mild or moderate inflammatory forms of acne vulgaris (papulopustular acne, grade I-II)

Dosage and administration form

Nadixa Cream should be applied as a thin layer to acne lesions twice a day, once in the morning and again before retiring to bed, after carefully clean and dry the affected areas. Caution should be used with eyes and lips. To avoid infections, Nadixa Cream should be applied using a swab. Nadixa should not be used under occlusive conditions. The duration of the treatment is, in general, up to 8 weeks but can be extended up to a maximum of 12 weeks if this is considered as acceptable from a medical point of view.

Contraindications

Nadixa is contraindicated in cases of known hypersensitivity to Nadifloxacin or any of the excipients of the formulation.

Warnings and special Precautions for use

The safety and effectiveness of Nadixa have not been studied enough in children younger than 14 years. Therefore, it is advisable not to use it in patients of this age group. Contact with eyes and other mucous membranes should be avoided. In case of contact, wash the eyes or mucous membrane with abundant warm water. Wash your hands after the application of the cream to avoid the accidental application to other areas. It is known that photosensitivity reactions have been developed in patients treated with other quinolones systemically administered. Although several studies in animals and humans have shown that Nadifloxacin has no phototoxic or photoallergic effect, the cream base can maximize the effect over the photosensitivity. In addition, there is no experience regarding the prolonged exposition to solar light or artificial UV light when Nadixa is used. Therefore, patients under treatment with Nadixa should avoid the exposition to artificial UV radiation (UV lamps, solar beds, solarium) and avoid when possible the exposition to solar light. If there is sensitization or severe irritation, discontinue the use of the product. The drug should not be applied to damaged skin (cuts and grazes) There are no data regarding the safety in concomitant use with other acne treatments (for example, benzoyl peroxide), therefore, Nadixa should only be used in monotherapy.

Pregnancy and Lactation

There are no data from controlled clinical trials regarding the effects of Nadifloxacin in pregnant women. Studies with animals have proved that there is not teratogenic risk or any other foetus/embryo toxic effects or effects to the postnatal development of the litter. During the pregnancy, Nadixa should only be used after careful evaluation of the expected benefit for the mother against the potential risks to the child development. It is known that Nadifloxacin is excreted with human milk and for that reason Nadixa should not be used during the nursing period. Women during nursing period should not apply, in any circumstance, Nadixa on their breast.

Effects on ability to drive and use machines

Neither the pharmacodynamic profile, nor the clinical experience suggest that Nadifloxacin could have any effect on the ability to drive and use machines.

Interaction with other drug products and other forms of interaction

The absorption of Nadifloxacin after the application of Nadixa to the human skin is very low and therefore the interaction with other drugs concomitantly administered by systemic route is very unlikely. There is no evidence that shows that the effectiveness of systemically administered drugs could be influenced by the topical use of Nadixa. Nadixa can produce skin irritation and thus it is possible that its use together with peeling agents, astringents and products containing irritant substances as aromatic agents and alcohols, can result in an increase in the skin irritation.

Adverse reactions

During the treatment with Nadixa it has been observed that skin alterations or irritation can be produced. These are shown as pruritus, burning sensation, erythema, contact dermatitis and urticaria. Skin hypopigmentation is also described in rare reports.The treatment should be discontinued in case of sensitivity or severe irritation.

Overdosage

Nadixa is intended for topical use and not for oral administration. Repeated and excessive applications do not accelerate or improve the therapeutical recovery and, on the other hand, they bear a risk of marked reddishness and discomfort.

In case of involuntary oral ingestion and unless the quantity of Nadixa accidentally ingested was small, a suitable method of gastric lavage should be considered.

Incompatibilities

None known

How supplied

Tubes containing 25 g of cream

Drugs should be kept out of the reach and sight of children.

Manufactured by: Ferrer Internacional, S.A., Barcelona, Spain