Naflox® 0.3% eye drops, solution

FARMIGEA

S01AX12 Norfloxacin

Generic medicine

Composition
100 ml of solution contain: *Active substance:* Norfloxacin 300mg
Excipients: Sodium acetate; benzalkonium chloride, sodium edetate; sodium chloride; water for injection.

Pharmaceutical form and content
Eye drops, solution 10ml bottle

Pharmacotherapeutic category
Ophthalmologic – Antimicrobial

Marketing authorisation holder
FARMIGEA S.p.A. - Via G. B. Oliva, 8 – 56121 Pisa, Italy
Manufacturer and final control
FARMIGEA S.p.A. - Via G. B. Oliva, 8 – 56121 Pisa, Italy

Therapeutic indications
Naflox® eye drops solution is indicated in the treatment of superficial infections of the eye and its complications caused by norfloxacin sensible bacteria.

Contraindications
Known hypersensitivity to any of the components of the drug or to any antibacterial agent chemically correlated to chinolons.

Precautions for use
The product contain benzalkonium chloride as a preservative, do not use while you are wearing contact lenses. Before wearing contact lenses wait 15-30 minutes after administration.

Interactions
Inform your doctor if you take any medicines or you would like to take including eye drops and self-medication products.

Special warnings
Pregnancy
There are no sufficient clinical investigation in pregnant women, but considering that systemic use of chinolonics may cause arthropathy in immature animals, therapy with Naflox® is not recommended in pregnancy. However, the quantity of active substance in the eye drop formulation, used to treat superficial infections in the eye, is far less than the dose used in systemic therapy.
Lactation
It is not known if norfloxacin is excreted in maternal milk after ocular administration, therefore the use of Naflox® in lactation is not recommended.
Effects on the capability to drive vehicles and use of machines
The substance does not interfere with the ability to drive or operate machinery. However immediately after instillation Naflox® can feel burning or stinging pain.

Before driving or using machines be sure that you are confortable with it.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Posology and method of administration
The usual dose is 1-2 drops of Naflox® eye drops in the eye 4 times daily. According to the severity of the infection the first day therapy dose can be 1-2 drops every 2 hours during the wake-up hours. A suitable monitoring of the bacterial response to the topical antibiotic therapy should be adopted the use of Naflox® eye drops.
Overdose
In case you instill too many drops in the eye or ingest accidentally the content of the bottle inform your doctor immediately.

Undesirable effects
The most frequently reported adverse effect was a burning feeling or stinging pain. Other rarely reported drug-related side effects include conjunctival hyperaemia, chemosis, photophobia and a bitter taste in mouth after instillation. By following carefully the instructions described in this leaflet reduces the risks of undesirable effects.
Please inform you doctor in case you experience any undesirable effect also not reported in this leaflet.

Expiry date and storage
Check the expiry dated reported on the package, it refers to the unopened correctly stored product.
Attention: do not use the product after the expiry date indicated on the package.
After opening the bottle use the product within 30 days and discard the remaining part.

Instructions for use
To open, press the closing cap while twisting off. Push carefully on the body of the bottle and drop the solution in the eye. After use, screw back tight.

Last revision of the text: June 2006