**STERILE OPHTHALMIC SOLUTION**

**CHLORAMPHENICOL**

**NORFLOXACIN**

**DESCRIPTION**

NORFLOXACIN ophthalmic solution is a synthetic 1,4-dihydropyridine derivative, an oral and topical antibacterial agent for the treatment of ocular infections.

**CLINICAL PHARMACOLOGY**

NORFLOXACIN has in vitro activity against a broad spectrum of susceptible aerobic, micro-aerophilic, and anaerobic bacteria. It is active against a range of bacteria that are commonly isolated from ocular infection sites.

**INDICATIONS AND USAGE**

**CHLORAMPHENICOL** is indicated for the treatment of infections caused by susceptible strains of the following organisms:

- Acinetobacter baumannii
- Acinetobacter calcoaceticus
- Aeromonas hydrophila
- Aeromonas hydrophila
- Proteus mirabilis
- Pseudomonas aeruginosa
- Salmonella typhosa
- Staphylococcus aureus
- Streptococcus pneumoniae

**CONTRAINDICATIONS**

**CHLORAMPHENICOL** is contraindicated in patients with a history of hypersensitivity to norfloxacin, or to other members of the quinolone antimicrobial class of antiseptic agents, or any other component of this medication.

**PRECAUTIONS**

**GENERAL**

As with other antibiotics, prolonged use may result in the development of non-resistant organisms. The patient should be instructed to use the solution at the prescribed frequency.

**ADVERSE REACTIONS**

- **General**
- **Skin**
- **GI**
- **Central nervous system**
- **Hematologic**

**PREPARATION AND ADMINISTRATION**

The recommended dose in adults and pediatric patients is 1 drop of solution in 1 eye (1.5 mg) once or twice daily. Dosage should be individualized.

**ADDITIONAL CAUTIONARY INFORMATION**

NORFLOXACIN is available in oral dosage forms as well.

**ANIMAL PHARMACOLOGY**

The oral administration of single doses of norfloxacin, six times the recommended human oral dose, caused increased urinary bladder, kidney, and liver weights in rats. Concurrent kidney and liver distress in rats and mice caused decreased feeding and growth rates.

**NURSING MOTHERS**

It is not known whether norfloxacin is excreted in human milk. When a treatment course is necessary, the decision should be made to discontinue breastfeeding or to discontinue the drug for the mother to the child.

**Pediatric Use**

Safety and effectiveness in infants below the age of one year have not been established.

**PREGNANCY**

NORFLOXACIN has been shown to be active in vitro against many strains of bacteria known to be clinically significant in infections of the eye. While there is no evidence of harm in laboratory animals, the long-term potential for harm in humans is unknown. Given the potential for toxicologic effects of the drug in the eye when administered in high doses, the use of the drug in pregnant women is not recommended.

**LACTATION**

It is not known whether norfloxacin is excreted in human milk. When a treatment course is necessary, the decision should be made to discontinue breastfeeding or to discontinue the drug for the mother to the child.

**REFERENCES**

For complete details, see the full prescribing information.

**Supplied Forms**

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**PATIENT INFORMATION**

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