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Cravit® ophthalmic solution

(Levofloxacin hydrate 0.5%)



Levofloxacin hydrate exerts a broad-spectrum potent antibacterial activity against organisms causing ophthalmological infections, including gram-positive bacteria, gram-negative bacteria and anaerobic bacteria. Levofloxacin hydrate, an optical isomer of Ofloxacin (*l*-form), has two times potent antibiotic activity than Ofloxacin.

[Composition]

Cravit ophthalmic solution is a clear, pale yellow to light yellow sterile aqueous ophthalmic solution. Each mL contains 5 mg of levofloxacin hydrate. Its pH is 6.2-6.8 and its osmotic pressure ratio is 1.0-1.1.

[Indications]

The following infections caused by levofloxacin-susceptible strains of *Staphylococcus* sp., *Streptococcus* sp., *Streptococcus pneumoniae*, *Micrococcus* sp., *Enterococcus* sp., *Corynebacterium* sp., *Pseudomonas* sp., *Pseudomonas aeruginosa*, *Haemophilus* sp. (*H. influenzae*, *H. aegyptius* [*Koch-Weeks bacillus*]), *Moraxella* (*Branhamella*) *catarrhalis*, *Moraxella* sp. (*Morax-Axenfeld bacillus*), *Serratia* sp., *Klebsiella* sp., *Proteus* sp., *Acinetobacter* sp., *Enterobacter* sp., *Propionibacterium acnes* :

Blepharitis, hordeolum, dacryocystitis, conjunctivitis, tarsadenitis, keratitis, corneal ulcer, and postoperative infections.

[Dosage and Administration]

Usually, instill 1 drop a time 3 times daily. The dosage may be adjusted according to the patient's symptoms.

[Pharmacology]

1. Antibacterial activity

1) Antibacterial activity

Levofloxacin hydrate exerts a broad-spectrum potent antibacterial activity against organisms causing ophthalmological infections, including gram-positive bacteria (*Staphylococcus* sp., *Streptococcus* sp. [including *S. pneumoniae*], *Micrococcus* sp., *Enterococcus* sp., *Corynebacterium* sp., etc.), gram-negative bacteria (*Pseudomonas* sp. [including *P. aeruginosa*], *Haemophilus* sp., *Moraxella* (*Branhamella*) *catarrhalis*, *Moraxella* sp., *Serratia* sp., *Klebsiella* sp., *Proteus* sp., *Acinetobacter* sp., *Enterobacter* sp., etc.), and anaerobic bacteria (*Propionibacterium acnes*, etc.).

The antibacterial activity of levofloxacin hydrate against standard strains for each bacteria and clinically isolated bacteria identified in patients with external ocular infections was about twice as potent as that of Ofloxacin (*in vitro*).

2) Effect on experimental *Pseudomonas aeruginosa* keratitis in rabbits

Levofloxacin hydrate ophthalmic solution was effective in preventing experimental *P. aeruginosa* keratitis in rabbits.

2. Mechanism of action

Main mechanism of action of levofloxacin hydrate is to inhibit DNA gyrase activities of bacteria. Its effect is two times greater than that of Ofloxacin. There was no difference between MICs and MBCs, indicating its effect being bactericidal. Also bacteriolysis around the MICs was shown in morphological observation.

[Contraindications] (Cravit ophthalmic solution is contraindicated in the following patients.)

Patients with a history of hypersensitivity to the ingredient of this product, Ofloxacin or any quinolone antibiotics.

参製薬	参天製薬
品名	クラビット点眼液 (シンガポール)添付文書
本品表	
寸法	254×110
出力	瓶式 オフ 正誤 MAC
使用色	紺
製作	凸版印刷
文字	新規 今井 31.03.14 訂正 六車 01.10.10
	757100シンガポール 07

[Precautions]

1. Adverse Reactions

1) Clinically significant adverse reactions

Shock, anaphylactoid reaction (incidence unknown) :
Since shock and anaphylactoid reaction may occur, patients should be carefully observed. If any symptoms such as erythema, rash, dyspnoea, decreased blood pressure, and eyelid oedema, etc. are observed, administration should be discontinued and appropriate measures should be taken.

2) Other adverse reactions

If the following adverse reactions are observed, appropriate measures such as discontinuing administration should be taken.

Incidence Type	Incidence unknown	5% > ≥0.1%	<0.1%
Hypersensitivity	Rash	—	Urticaria, blepharitis (redness of eyelid and eyelid oedema, etc.), dermatitis eyelid, itching
Ophthalmic	—	Irritation, corneal disorder including keratitis superficial diffuse, etc.	Conjunctivitis (conjunctival hyperaemia and conjunctival oedema, etc.), eye pain

2. General precaution

- 1) In order to avoid the emergence of resistant bacteria, bacterial susceptibility should be confirmed and treatment with this drug should be limited to the minimum period required for the eradication of the infection.
- 2) The efficacy of this product to methicillin-resistant *Staphylococcus aureus* (MRSA) has not been proved. Therefore, other drug having a potent anti-MRSA activity should be administered immediately to patients positively infected with MRSA and not showing any improvement of symptoms with this product.

3. Use during Pregnancy

This product should be used in pregnant women or women who may possibly be pregnant only if the expected therapeutic benefits are judged to outweigh the possible risks associated with treatment. [The safety of this product during pregnancy has not been established.]

4. Precautions concerning Use

- 1) Route of administration : Ophthalmic use only.
- 2) At the time of administration : Instruct the patient to be careful not to touch the tip of the bottle to the eye directly in order to avoid the contamination of the drug.

[Storage]

Store at or below 30°C in a tight container under protection from light.

[How Supplied]

Plastic bottle of 5 mL

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Manufactured by:

SANTEN PHARMACEUTICAL CO., LTD.

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CV-SIN

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