Effexin® otic solution

(Ofloxacin Ear Drops)

COMPOSITION

Active: Ofloxacin 0.3% (3mg/ml)
Preservative: Benzalkonium Chloride 0.0025%

PHARMACOLOGY

Ofloxacin has in vitro activity against a broad range of gram-positive and gram-negative microorganisms such as Staphylococcus spp. and Pseudomonas aeruginosa which may cause otitis media and otitis externa.

Pharmacokinetics

Drug concentration in mucosa of the middle ear is more than 40mcg/g and Effexin® otic solution is efficacious against otic infections.

INDICATION

Effexin® otic solution is indicated for the treatment of infections such as otitis media and otitis externa caused by susceptible strains of the designated micro-organisms such as Staphylococcus spp., Streptococcus spp., Proteus spp., Pseudomonas aeruginosa, Haemophilus influenza and etc.

Recommended Dose

For adults, instill six to ten drops into the affected ear(s) twice daily. The patient should lie with the affected ear upward, and the drops should be instilled and this position should be maintained for about 10 minutes to facilitate penetration of the drops into the ear canal. Dosage should be adjusted appropriately based on age and symptoms.

Mode of administration Intra-canal.

Contraindication

Hypersensitivity to ofloxacin or other quinolones or any other component of the medication.

Warnings / Precautions

1) Check the susceptibility and administer the drug only for the least needed period to prevent drug resistant bacterium from onset.
2) A standard period of administration of this drug is 4 weeks and additional administration after 4 weeks needs caution.
3) As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi and Effexin® otic solution should not be used in a long period. If superinfection occurs, discontinue use and institute alternative therapy.
4) If otorrhea persists after a full course of therapy, or if two or more episodes of otorrhea occur within six months, further evaluation is recommended to exclude an underlying condition such as cholesteatoma, foreign body, or a tumor.

※(MY)5000000-1240814

5) Otic solution is administered when inflammation is in mucosa of the middle ear locally. In case that inflammation spreads to around tympanum, oral administration should be considered along with otic administration.

6) Exacerbation of myasthenia gravis: Fluoroquinolones have neuromuscular blocking activity and may exacerbate muscle weakness in person with myasthenia gravis. Post marketing serious adverse events, including deaths and requirement for ventilator support have been associated with fluoroquinolones use in persons with myasthenia gravis. Avoid fluoroquinolones in patients with known history of myasthenia gravis.

Drug Interactions

Specific drug interaction studies have not been conducted with Effexin® otic solution.

Use in Pregnancy

There are no adequate and well-controlled studies in preganat women.
Effexin® otic solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in Lactation

It is not known whether ofloxacin is excreted in human milk following topical otic administration. Because of the potential for serious adverse reactions from Ofloxacin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Adverse Effects

Hypersensitivity reactions include cardiovascular collapse, loss of consciousness, angioedema, airway obstruction, dyspnea, urticaria, and itching. In this case, medication should be discontinued. Otitis externa: Priritus, dizziness and earache may occur. Other treatment-related : Nausea, vomiting, dry mouth, headache, vertigo and etc. may occur.

Exacerbation of myathenia gravis
Post Marketing Experience

Symptoms and Treatment of Overdose

In the event of a topical overdosage, flush the eye with water.

Packing / Pack Sizes

Effexin® Otic Solution 0.3% x 5ml / bottle.

Product Description

Light yellowish transparent solution.

Storage Conditions

Store in a tight container below 30°C.

Shelf-life 36 months from the date of manufacture. Discard within 30 days after first opening.

Date of Revision : 14th August 2024

Manufactured by: **Hanlim Pharm Co., Ltd.**
2-27, Yeongmun-ro, Cheoin-gu, Yongin-si, Gyeonggi-do, Republic of Korea.

※(MY)5000000-1240814

설명서	에펙신(말레이시아) 이용액	
학술담당	디자인담당	품질담당
강예지 차장	오인호 차장	송경문 대리
	변경 전	현재
화판번호		(MY)5000000-1240814
사이즈(mm)		120 x 175
지질/평량		모조지 50G
코팅		무코팅
변경 내역	변경 갱신용(=임시화판) =갱신후에 본품화판에 내용반영	
비고		
인쇄소		

색상	
	K

후가공	

별색판 / 중복인쇄 확인할 것