Ofloxacin

[TOFL] Ofloxin<sup>®</sup> Otic Solution 3mg/mL, 5mL/Bot ATC Code: S02AA16

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適應症: 成人及小兒外耳炎、成人及青少年鼓膜穿孔之慢性中耳炎、裝有鼓膜造口管的

小兒急性中耳炎。

藥理分類: Antibiotic, Fluoroquinolone; Otic. 用法用量: **Administration:** for Otic use only.

- Prior to use, warm solution by holding container in hands for 1 to 2 minutes.
- Patients should remain in this position for 10 minutes to allow penetration of solution.

## **Indications and Dosage regimens:**

**Adults:** 

Otitis media, chronic suppurative (with perforated tympanic membranes):

Instill 10 drops into affected ear(s) twice daily for 14 days

**Otitis externa:** 

Instill 10 drops into affected ear(s) once daily for 7 days.

Pediatric:

Otitis media, acute (with tympanostomy tubes):

**Children:** 

Instill 5 drops (0.25 mL) into the affected ear(s) BID for 10 days.

Otitis media, chronic suppurative (with perforated tympanic membranes):

Children ≥12 years and Adolescents:

Instill 10 drops (0.5 mL) into the affected ear(s) twice daily for 14 days.

Otitis externa, acute:

**Infants ≥6 months and Children:** 

Instill 5 drops (0.25 mL) into the affected ear(s) once daily for 7 days.

**Adolescents:** 

Instill 10 drops (0.5 mL) into the affected ear(s) once daily for 7 days.

不良反應: 頭痛、耳痛、外耳道發紅。過敏性反應。

注意事項: 1.本劑僅可以點耳法使用,做為中耳炎局部治療之用,若發炎的情形延伸至鼓室周圍,則必須配合口服藥做全身性治療。

2.如果藥水冰冷,滴入時容易發生暈眩的情形,故儘可能在與體溫相近的情形 下使用本劑,**滴入後讓藥水停留約10分鐘**。

懷 孕 期: 1. Adverse events have been observed in some animal reproduction studies.

2. When administered orally, ofloxacin crosses the placenta (Giamarellou 1989). The amount of ofloxacin available systemically following topical application of the otic drops is significantly less in comparison to oral doses.

授 乳 期: 1. When administered orally, ofloxacin enters breast milk. It is not known if ofloxacin can be detected in breast milk following otic administration.

2.Due to the potential for serious adverse reactions in the nursing infant, the manufacturer recommends a decision be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of treatment to the mother.

储 存: 於25℃以下儲存。