

OFLOMED®
0.3% Otic Solution

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about OFLOMED

Oflomed otic solution is an ear drop containing 0.3% ofloxacin with the following excipients: glycerin, benzalkonium chloride, sodium chloride and purified water.

Ofloxacin is a quinolone antibiotic used to treat ear infections such as: middle ear infection and external ear canal infection caused by certain bacteria.

Oflomed otic solution is indicated in the following conditions:

- Chronic suppurative otitis media in patients (12 years and older) with perforated tympanic membranes
- Acute otitis media in pediatric patients (between 1 and 12 years of age) with tympanostomy tubes
- Otitis externa in adults and pediatric patients (6 months and older)

The way to use OFLOMED

Use according to your doctor's instructions.

Step 1: The person giving Oflomed should wash his/her hands with soap and water.

Step 2:

- Gently clean any discharge that can be removed easily from the outer ear without inserting any object or swab into the ear canal.
- Hold the bottle in the hand for one or two minutes to warm the solution.
- The tip of the bottle should not touch the fingers or the ear or any other surfaces.
- The person receiving Oflomed should lie on his/her side with the infected ear up. This position should be remained for five minutes after Oflomed administration to facilitate penetration of the drops into the ear canal.

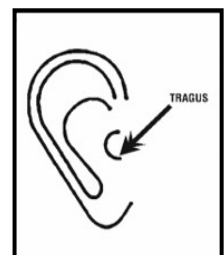
Step 3: Administer the recommended number of drops into the ear as follow:

Indication	Dosage	Duration of treatment
Chronic suppurative Otitis media with perforated tympanic membranes	Patients (12 and older): 10 drops put into the infected ear	Twice daily for 14 days
Acute otitis media with tympanostomy tubes	Pediatric patients (1 - 12 years): 5 drops put into the infected ear	Twice daily for 10 days
Otitis externa	Patients (13 years and older): 10 drops put into the infected ear.	Once daily for 7 days
	Pediatric patients (6 months - 13 years): 5 drops put into the infected ear.	

Step 4: Press ear or pull ear.

- For a Middle Ear Infection:

While the person receiving Oflomed lies on his/her side, the person giving the drops should gently press the TRAGUS 4 times in a pumping motion. This will allow the drops to pass into the middle ear.



- For an External Ear Canal Infection:

While the person receiving the drops lies on his/her side, the person giving the drops should gently pull the outer ear upward and backward. This will allow the ear drops to flow down into the ear canal.



Step 5: Repeat Steps 2-4 for the other ear if both ears are infected.

In case of overdose

In case of the intake of this medication accidentally by mouth or in case of overdose, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Administer the missed dose as soon as you remember and continue with the regular schedule unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in case of hypersensitivity to ofloxacin or to any of the ingredients

Precautions

- OfloMed is not for eye use and not for injection.
- Avoid swimming or getting the ear wet when bathing during treatment.
- It is not recommended to use ofloxacin in case of pregnancy or lactation, ask your doctor before using this medication.

Associations with other medications

Please inform your doctor if you are using any other medication.

Adverse reactions

The most commonly reported adverse reactions include: discomfort upon application, bitter taste.

Other adverse reactions have also been reported such as: earache, itching or dizziness.

Inform your doctor if any adverse reaction appears or becomes bothersome.

Storage

Store at controlled room temperature (below 30°C), protected from light and humidity, beyond the reach of children. Do not freeze. The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

OFLOMED, ofloxacin 0.3% otic solution, bottle of 5mL

Issue date: 03/2024

OFLK03/001

Marketing Authorisation Holder and Manufacturer: Mediphar Laboratories - Lebanon