SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

OFLOCET 1.5 mg/0.5 mL, otic solution in single-dose container

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ofloxacin ..... 1.5 mg
Per single-dose container
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Otic solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Local treatment of purulent otorrhoea:

- in patients with tympanostomy tubes,
- in open mastoid cavity,
- in chronic non-osteitic otitis media with perforated tympanic membrane.

Note: no studies have been conducted in otitis externa.

Official guidelines on the appropriate use of antibacterial agents should be considered.

4.2. Posology and method of administration

Posology

- Instill, each morning, the entire contents of one single-dose container (approximately 10 drops) into the external auditory canal of the affected ear, and repeat the procedure in the evening.
- The usual duration of treatment is 7 days.
- If symptoms persist after 10 days, the patient should be reassessed and the diagnosis and treatment reconsidered.

Method of administration

- For otic use only
- Detach one single-dose container from the strip (Figure 1).
- Warm the single-dose container before use by holding it in the palm of the hand for a few minutes.
- Open the single-dose container by twisting off the cap (Figure 2).
- Invert the container to allow the solution to flow towards the nozzle.
- With the head tilted, instill the entire contents of the single-dose container into the external auditory canal of the affected ear, gently pulling the auricle several times (Figure 3).
- Keep the head tilted to one side for approximately 5 minutes to facilitate penetration of the drops into the external auditory canal.
- Repeat, if necessary, in the other ear using a new single-dose container.
- Discard the single-dose container immediately after use (Figure 4).

4.3 Contraindications

This medicinal product must not be used in cases of hypersensitivity to ofloxacin or to other quinolones.

4.4 Special warnings and precautions for use

Hypersensitivity

The administration of topical antibiotics may lead to sensitisation to these active substances, with possible occurrence of systemic reactions.
Treatment must be discontinued at the first signs of skin rash or any other sign of local or systemic hypersensitivity.

Tendonitis and tendon rupture

Tendonitis and tendon rupture may occur with systemic fluoroquinolone therapy such as ofloxacin, particularly in elderly patients and in those treated concomitantly with corticosteroids. Therefore, OFLOCET 1.5 mg/0.5 mL, otic solution in single-dose container must be discontinued at the first signs of tendon inflammation.

Precautions for use

DO NOT INJECT, DO NOT SWALLOW, DO NOT APPLY TO THE EYE, DO NOT INHALE.
DO NOT USE OTHER THAN IN THE EAR.
At the time of administration, avoid contact of the tip with the ear or fingers in order to limit the risk of contamination.
This solution is supplied in a single-use container.
The single-dose container must be discarded immediately after use and must not be kept for reuse: since this product does not contain a preservative, there is a risk of rapid bacterial contamination.

4.5. Interaction with other medicinal products and other forms of interaction

Available data to date do not suggest the existence of clinically significant interactions.

4.6 Fertility, pregnancy and lactation

Pregnancy

Systemic exposure to ofloxacin appears negligible after administration of OFLOCET, otic solution. However, given the risk of joint disorders described in children treated with systemic quinolones, as a precautionary measure, it is preferable to avoid the use of OFLOCET, otic solution during pregnancy.

Breastfeeding

No effects on breastfed newborns/infants are expected, as systemic exposure to OFLOCET, otic solution in breastfeeding women is negligible. However, as a precautionary measure, this medicinal product should be avoided in breastfeeding women.

4.7 Effects on ability to drive and use machines

No effects on the ability to drive and use machines are expected, due to the route of administration and the low administered dose.

4.8 Undesirable effects

Frequencies are defined as follows: very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1,000, < 1/100); rare (≥ 1/10,000, < 1/1,000); very rare (< 1/10,000); and not known (cannot be estimated from the available data).

Ear and labyrinth disorders0
Rare: ear pain.

Immune system disorders
Rare: hypersensitivity reactions.

Musculoskeletal and connective tissue disorders (*)
Not known: tendon disorders.

(*) Tendon ruptures of the shoulder, hand, and Achilles tendon requiring surgical repair or resulting in prolonged disability have been reported in patients treated with systemically administered fluoroquinolones. Studies and post-marketing experience with systemic fluoroquinolones indicate that the risk of such ruptures may be increased in patients receiving corticosteroids (particularly in elderly patients) and in cases where tendons are subjected to high stress (including the Achilles tendon). To date, clinical and post-marketing data have not demonstrated a causal link between otic administration of ofloxacin and these musculoskeletal and connective tissue adverse events.

Reporting of suspected adverse reactions

The reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the FRILAB reporting form available under the pharmacovigilance section of the website: www.frilab.ch

4.9 Overdose
Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Otologicals, anti-infectives, ATC code: S02AA.
Ofloxacin is a synthetic antibiotic belonging to the quinolone class, specifically the fluoroquinolone group. Its antibacterial activity is strongly bactericidal through inhibition of bacterial DNA gyrase, thereby preventing the synthesis of bacterial chromosomal DNA.

Antibacterial spectrum
Breakpoints separating susceptible strains from those with intermediate susceptibility, and the latter from resistant strains are as follows:
S ≤ 1 mg/L and R > 4 mg/L.
The prevalence of acquired resistance may vary geographically and over time for certain species. It is therefore useful to have information on local resistance patterns, particularly when treating severe infections. These data provide only guidance on the probability of susceptibility of a bacterial strain to this antibiotic.
When the variability of resistance prevalence in France is known for a given bacterial species, it is indicated in the table below:

Categories	Frequency of acquired resistance in France (>10%) (ranges)
SUSCEPTIBLE SPECIES	
Gram-positive aerobes	
Bacillus anthracis **	
Methicillin-susceptible *Staphylococcus* *	
Gram-negative aerobes	
***Acinetobacter* (mainly *Acinetobacter baumannii*)**	**50–75 %**
Branhamella catarrhalis	
Bordetella pertussis	
Campylobacter	
Citrobacter freundii	**15–25 %**
Enterobacter cloacae	**15–25 %**
Escherichia coli	**0–10 %**
Haemophilus influenzae	
Klebsiella oxytoca	**0–11 %**
Klebsiella pneumoniae	**0–25 %**
Legionella	
Morganella morganii	
Neisseria	
Pasteurella	
Proteus mirabilis	**0–10 %**
Proteus vulgaris	
Providencia	**45–70 %**
Pseudomonas aeruginosa *	**45–85 %**
Salmonella	
Serratia	**40–45 %**
Shigella	
Vibrio	

Yersinia	
Anaerobes	
Mobiluncus	
Propionibacterium acnes	
Others	
Mycoplasma hominis	
MODERATELY SUSCEPTIBLE SPECIES	
(in vitro intermediate susceptibility)	
Gram-positive aerobes	
***Corynebacterium* spp.**	
***Streptococcus* spp.**	
Streptococcus pneumoniae	
Others	
Chlamydiae	
Mycoplasma pneumoniae	
Ureaplasma urealyticum	
RESISTANT SPECIES	
Gram-positive aerobes	
***Enterococcus* spp.**	
Listeria monocytogenes	
Nocardia asteroides	
Methicillin-resistant *Staphylococcus**	
Anaerobes	
except *Mobiluncus* and *Propionibacterium acnes*	

* Clinical efficacy has been demonstrated for susceptible strains in the approved clinical indications.
** The frequency of methicillin resistance is approximately 30% to 50% among all staphylococci and is mainly encountered in hospital settings.
*** *Bacillus anthracis*: no experimental animal infection studies in anthrax have been performed.

Atypical mycobacteria:
Ofloxacin shows moderate in vitro activity against certain mycobacterial species: *Mycobacterium tuberculosis*, *Mycobacterium fortuitum*; lower activity against *Mycobacterium kansasii* and even lower against *Mycobacterium avium*. Note: this spectrum corresponds to that of systemic forms of ofloxacin. With locally administered pharmaceutical forms, the concentrations achieved at the site of administration are significantly higher than plasma concentrations. Some uncertainties remain regarding in situ concentration kinetics, local physicochemical conditions that may modify antibiotic activity, and product stability at the site of administration.

5.2 Pharmacokinetic properties
In adults, serum concentrations of ofloxacin 30 minutes after a single instillation of 10 drops of a 0.3% solution (i.e. 1.5 mg of ofloxacin) are less than or equal to 0.002 µg/mL, and after repeated administration (10 drops every 12 hours for 7 days) range from 0.002 to 0.012 µg/mL.
In children, serum concentrations of ofloxacin after a single instillation are less than or equal to 0.013 µg/mL.
Systemic absorption of this formulation of ofloxacin is negligible; good diffusion with high concentrations at the site of infection is observed.

5.3 Preclinical safety data
Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Sodium chloride, hydrochloric acid and sodium hydroxide, purified water.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
3 years.

6.4 Special precautions for storage
Store protected from light.
Shelf life after opening: after use, the single-dose container must be discarded.
Do not reuse a previously opened single-dose container.

6.5 Nature and contents of container
0.5 mL in single-dose container (PE); box of 20.

6.6 Special precautions for disposal and handling
No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
TAMRISA ACCESS
22, Rue de la Fédération
75015 Paris - France

Export Distributor:
FRILAB SA
17 Rue des Pierres du Niton
1207 Geneva -Switzerland

8. MANUFACTURER
OPELLA HEALTHCARE INTERNATIONAL SA
56 Route de Choisy
60200 Compiègne - France

9. DATE OF REVISION OF THE TEXT
05/2025

10. DOSIMETRY
Not applicable.

11. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS
Not applicable.

CONDITIONS OF PRESCRIPTION AND SUPPLY

List I