

For UK Healthcare Professionals only

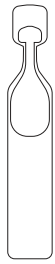
Acute otitis externa (AOE) treatment landscape

	Product ¹	Indication	Presentation	Dosing	Bi-daily (bd) dosing	Suitable for use in eardrum perforation	Preservative free	Non-ototoxic	Steroid	Cost ²
Fluoroquinolones	Cetraxal (ciprofloxacin 2mg/ml)	AOE in adults & children 1yr+ with an intact tympanic membrane	15 single-dose ampoules	1 ampoule bd, 7 days	✓	With caution	✓	✓	⊗	£6.01
	Cetraxal Plus (ciprofloxacin 3mg/ml + fluocinolone 0.25mg/ml)	AOE & AOM (acute otitis media) with tympanostomy tubes (AOMT), age 6mo+	15 single-dose ampoules	1 ampoule bd, 7 days	✓	✓	✓	✓	✓	£6.01
	ciprofloxacin 3mg/ml + dexamethasone 1mg/ml	AOMT (6 months +) & AOE (1 yr+)	5ml bottle	4 drops bd, 7 days	✓	✓	⊗	✓	✓	£6.12
	Ciloxan (ciprofloxacin 0.3% eye drops)	Corneal ulcers & superficial infections of the eye	5ml bottle	← Used off label →		⊗	✓	⊗	⊗	£4.70
Aminoglycosides	Otomize (neomycin sulphate 0.5% + dexamethasone 0.1% + glacial acetic acid 2%)	AOE (Age 2 yrs+)	5ml spray	3x daily, 7 days	⊗	⊗	✓	⊗	✓	£3.27
	Betnesol-N (neomycin sulphate 0.5% + betamethasone sodium phosphate 0.1%)	Otitis externa/steroid-responsive conditions where antibiotics required	10ml bottle	2-3 drops, 3-4x daily	⊗	⊗	⊗	⊗	✓	£2.39
	gentamicin 0.3% + hydrocortisone acetate 1% ear drops	Eczema/infection in outer ear (otitis externa)	10ml bottle	2-4 drops, 3-4x daily, and at night	⊗	⊗	⊗	⊗	✓	£33.26
	Otosporin (polymyxin B sulphate + neomycin sulphate + hydrocortisone)	Otitis externa due to bacterial infection	10ml bottle	3 drops, 3-4x daily	⊗	⊗	⊗	⊗	✓	£7.45
	Sofradex (framycetin sulphate 0.5% + dexamethasone sodium metasulphobenzoate 0.05% + gramicidin)	Otitis externa	8ml bottle	2-3 drops, 3-4x daily	⊗	⊗	⊗	⊗	✓	£7.50
Anti-fungal	flumetasone 0.02% + clioquinol 1% ear drops	Inflam. conditions of external ear, where 2° infection suspected	7.5ml bottle	2-3 drops bd, 7-10 days	✓	⊗	✓	✓	✓	£11.34

Prescribing information can be found on the reverse.

WHEN AOE STRIKES, YOU NEED A HERO

Fluoroquinolones are considered to be non-ototoxic³:



Cetraxal

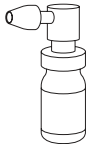
ciprofloxacin

Cetraxal Plus

ciprofloxacin + fluocinolone
0.25mg/ml

- Single dose ampoules
 - A study showed 94.4% patients found it easy to administer⁴
- Non-ototoxic and well tolerated
- Free from preservatives and known sensitizing agents
- Suitable for 6mo+ (Cetraxal Plus)⁵ and 1yr+ (Cetraxal)⁶
- Convenient dosing regimen: 1 ampoule bi-daily
- Tailored treatment options:
 - Cetraxal – steroid-free
 - Cetraxal Plus – can be used with known/suspected eardrum perforation

Aminoglycosides are known to be ototoxic and are contraindicated in perforated eardrum cases:



Otomize

neomycin + dexamethasone 0.1% +
glacial acetic acid 2%



gentamicin + hydrocortisone
acetate 1%

- Spray bottle
- Marked increase in resistance of *Pseudomonas* to neomycin^{7, 8}
- Suitable for 2yrs+
- Dosing regimen: 1 spray 3x daily
- Dropper bottle
- Contains benzalkonium chloride (BAK), a known sensitizing agent⁹
- Dosing regimen: 2-4 drops 3-4x daily and at night

1. Medicines.org.uk/emc (accessed September 2023). 2. Mims.co.uk (accessed September 2023). 3. Coates, H. Ear drops and ototoxicity. *Aust Prescr* 2008; 31 :40-1. 4. Dreihobl, M. et al. (2008) Comparison of efficacy and safety of ciprofloxacin otic solution 0.2% versus polymyxin B-neomycin-hydrocortisone in the treatment of acute diffuse otitis externa. *Current Medical* 24 (12): pp. 3531-3542. 5. <https://www.medicines.org.uk/emc/product/9805/smpc#ref> 6. <https://www.medicines.org.uk/emc/product/8847/smpc#ref> 7. Ninkovic, Get al, *Microbiology of otitis externa in the secondary care in United Kingdom and antimicrobial sensitivity Auris Nasus Larynx* 35 (2008) 480-484. 8. Cantrell, H.F. et al. (2004) Declining Susceptibility to Neomycin and Polymyxin B of Pathogens Recovered in Otitis Externa Clinical Trials. *South Med J.* 97(5):465-71 9. NICE Otitis Externa Prescribing Information. Available at: cks.nice.org.uk/otitis-externa#prescribingInfoSub (Accessed September 2023).

Cetraxal (ciprofloxacin) 2mg/ml ear drops solution in a single-dose container. Prescribing Information (please refer to the full SmPC before prescribing)

Indication: Acute otitis externa in adults and children older than 1 year with an intact tympanic membrane, caused by ciprofloxacin susceptible microorganisms. **Available strength** 0.50 mg ciprofloxacin contained in 0.25ml of solution. See the Summary of Product Characteristics (SmPC) for a full list of excipients. **Dosage and method of use:** Adults and children aged one year and older: Instil the contents of a single ampoule into the affected ear twice daily for seven days. Children aged less than one year: Safety and efficacy not established. **Method of administration:** Warm the ampoule in the hand for several minutes. Patient should lie with affected ear upward and instil drops, pulling on auricle several times. Maintain position for 5 minutes to facilitate penetration. For further administration details, please see SmPC. If otowick/tampon is used for administration, double the first dose to two ampoules. Use immediately after opening the ampoule. Discard any unused contents. No dose adjustment required in those with renal or hepatic impairment. **Contraindications:** Hypersensitivity to ciprofloxacin, any member of the quinolone class or listed excipients. **Special warnings and precautions for use:** Not for ophthalmic use, inhalation or injection. Monitor use carefully to determine if other therapy may be required. If after one week of therapy, signs and symptoms persist, re-evaluate further. Safety and efficacy not established under 1 year of age. Weigh benefits against known and unknown risks of prescribing in those under 1. Use with caution if known or suspected perforated tympanic membrane and where there is a risk of perforation. Discontinue use at first appearance of a skin rash or any other sign of hypersensitivity. Some patients taking systemic quinolones have shown moderate to severe skin sensitivity to the sun. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some after the first dose of a systemic quinolone. Serious acute hypersensitivity reactions may require immediate emergency treatment. Overgrowth of non-susceptible organisms may occur from use including bacterial strains, yeast and fungi. If superinfection occurs, treat as appropriate. **Interactions with other medicinal products:** No interaction studies performed. Due to low plasma levels, systemic interactions unlikely. Recommendation not to use other ear preparations concomitantly. **Pregnancy and breast-feeding:** Can be used during pregnancy and breast-feeding. **Effects on ability to drive and use machines:** None or negligible. **Side effects:** For full list of side effects consult the SmPC. Ear pruritis, headache, application site pain, tinnitus, dizziness, dermatitis. Very rarely with locally applied fluoroquinolones: rash, toxic epidermolysis, exfoliative dermatitis, Stevens-Johnson syndrome, urticaria. **MAH:** Aspire Pharma Ltd, Unit 4, Rotherbrook Court, Bedford Road, Petersfield, Hampshire, GU32 3QG, United Kingdom **MA number:** PL35533/0130. **Cost:** Per pack of 15 ampoules £6.01 **Legal Category:** POM. **Date reviewed:** August 2023 **Version number:** 1010385675 v 4.0

Cetraxal Plus (ciprofloxacin and fluocinolone acetonide) 3mg/ml + 0.25mg/ml ear drops solution in a single-dose container. Prescribing Information (please refer to the full SmPC before prescribing)

Indication: Acute otitis externa and acute otitis media in patients with tympanostomy tubes, in adults and children aged 6 months and older, caused by ciprofloxacin susceptible microorganisms. **Available strength:** 0.75 mg ciprofloxacin and 0.0625 mg of fluocinolone acetonide, contained in 0.25ml of solution. Please refer to the Summary of Product Characteristics (SmPC) for a full list of excipients. **Dosage and method of use:** Adults, elderly and children aged 6 months and older: Instil the contents of one single-dose container into the affected ear canal every 12 hours for 7 days. **Renal/hepatic impairment:** no dose adjustment necessary. Warm bottle by holding in hand for several minutes. Lie with affected ear upwards - for patients with otitis externa, pull the auricle several times during instillation. For patients with acute otitis media with tympanostomy tubes, pump the tragus 4 times by pushing inward to facilitate penetration. This position should be maintained for around 1 minute. For further details, please refer to the SmPC. **Contraindications:** Hypersensitivity to ciprofloxacin, any member of the quinolone class, fluocinolone acetonide or listed excipients. Viral infections of the external ear canal, including varicella and herpes simplex infections and fungal otic infections. **Special warnings and precautions for use:** Not for ophthalmic use, inhalation or injection. Should not be swallowed. If otorrhea persists after full course of therapy or if two or more episodes occur within six months, evaluate further. If after treatment signs and symptoms persist, evaluate further. Discontinue at first appearance of a skin rash or any other sign of hypersensitivity. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some after the first dose of a systemic quinolone. Serious acute hypersensitivity reactions may require immediate emergency treatment. Overgrowth of non-susceptible organisms may occur from use including bacterial strains, yeast and fungi. If superinfection occurs, treat appropriately. Some patients taking systemic quinolones have shown moderate to severe skin sensitivity to the sun. Corticosteroids may reduce resistance to, and aid in, the establishment of bacterial, viral or fungal infections and mask the clinical signs of an infection, ineffectiveness of the antibiotic or suppress hypersensitivity reactions. If patient presents with blurred vision or other visual disturbances, consider referral to ophthalmologist for evaluation of causes e.g. cataract, glaucoma, central serous chorioretinopathy. Safety and efficacy not established in children under 6 months - only use after very careful benefit/risk evaluation. **Interactions with other medicinal products:** No interaction studies performed. Due to low plasma levels, systemic interactions unlikely. Systemic administration of some quinolones may enhance the effects of warfarin and its derivatives and has been associated with transient serum creatinine elevations in patients receiving concomitant cyclosporine. Recommendation not to use other ear preparations concomitantly; if more than one is needed, administer them apart. **Pregnancy and breast-feeding:** For full details please refer to the SmPC. **Pregnancy -** Assess whether benefits of the treatment outweigh the possible risk. Caution when administered to a nursing woman. **Effects on ability to drive and use machines:** None or negligible. **Side effects:** For full list of side effects consult SmPC. 'Very Common' 'Common' and 'Serious' side effects included in prescribing information: dysgeusia, ear pain, ear discomfort, ear pruritus. **MAH:** Aspire Pharma Ltd, Unit 4, Rotherbrook Court, Bedford Road, Petersfield, Hampshire, GU32 3QG, United Kingdom **MA number:** PL35533/0133. **Cost:** Per pack of 15 ampoules £6.01 **Legal Category:** POM. **Date reviewed** August 2023. **Version Number:** 1010385676 v 4.0

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Aspire Pharma Ltd on 01730 231148.