

# Otodolor® eardrops/Otodolor® forte eardrops: a topical treatment of otitis externa

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| <b>Submission date</b><br>08/10/2009   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>22/10/2009 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>03/11/2009       | <b>Condition category</b><br>Ear, Nose and Throat | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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Austria  
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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Safety and efficacy of the homeopathic remedies Otodolor® eardrops/Otodolor® forte eardrops for topical treatment of otitis externa: a non-interventional trial

**Acronym**

**Study objectives**

Systematic and prospective data collection on safety and efficacy of homeopathic remedies (Otodolor® eardrops/Otodolor® forte eardrops) for topical treatment of otitis externa in children and adults in the common general practice of ear, nose and throat (ENT) doctors or paediatricians. This trial will assess the following:

1. The reduction of subjective and objective complaints like redness, swelling, eczematous affections, secretion, ear pain and itching
2. The reduction of other otitis externa medications under therapy
3. Safety data (adverse drug reactions [ADRs])

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Submission of a non-interventional study to Regulatory Board/Ethics Committee is not necessary in Austria until after June 2010.

**Study design**

Open longitudinal multicentre non-interventional trial

**Primary study design**

Observational

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Otitis externa

**Interventions**

Otodolor® eardrops (every 2 - 4 hours, 3 - 5 drops/ear) or Otodolor® forte eardrops (every 2 - 4 hours, 3 - 5 drops/ear) for topical treatment of otitis externa over a 2-week period.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Otodolor® eardrops/Otodolor® forte eardrops

**Primary outcome(s)**

1. The reduction of subjective and objective complaints like redness, swelling, eczematous affections, secretion, ear pain and itching
2. The reduction of other otitis externa medications under therapy

**Key secondary outcome(s)**

Safety assessment (adverse drug reactions [ADRs])

**Completion date**

01/05/2009

## Eligibility

**Key inclusion criteria**

1. Patients with acute or chronic otitis externa presenting to ENT doctors or paediatricians
2. Children aged 6 years onwards and adults (either sex) for Otodolor® eardrops
3. Children aged 12 years onwards and adults (either sex) for Otodolor® forte eardrops

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Other

**Sex**

All

**Key exclusion criteria**

1. Patients under the age of 6 years
2. A known or suspected perforation of the eardrum

**Date of first enrolment**

01/09/2008

**Date of final enrolment**

01/05/2009

## Locations

**Countries of recruitment**

Austria

**Study participating centre**

Specialist for ENT Surgery

Vienna

Austria

A-1060

## Sponsor information

**Organisation**

Dr. Peithner KG nunmehr GmbH & Co (Austria)

**ROR**

<https://ror.org/00wcjzh22>

**Funder(s)****Funder type**

Industry

**Funder Name**

Dr. Peithner KG nunmehr GmbH & Co (Austria)

**Results and Publications****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |