

**TRANSLATION OF CURRENT GERMAN PACKAGE LEAFLET ACCORDING TO
GERMAN MARKETING AUTHORISATION:**

Package leaflet: Information for the user

Otovowen[®]
Mixture for oral use

Active substances:

Aconitum napellus Dil. D6; Capsicum annuum Dil. D4; Chamomilla recutita Ø; Echinacea purpurea Ø; Hydrargyrum bichloratum Dil. D6; Hydrastis canadensis Dil. D4; Iodum Dil. D4; Natrium tetraboricum Dil. D4; Sambucus nigra Ø; Sanguinaria canadensis Ø.

**Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to take Otovowen[®]
carefully to get the best results from it.**

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Otovowen[®] is and what it is used for
2. What you need to know before you take Otovowen[®]
3. How to take Otovowen[®]
4. Possible side effects
5. How to store Otovowen[®]
6. Further information

1. WHAT OTOVOWEN[®] IS AND WHAT IT IS USED FOR

Otovowen[®] is a homeopathic medicine for inflammation of the middle ear.

Therapeutic indications:

The indications are derived from the homeopathic remedy profiles.

These include: Relief of the symptoms of inflammation of the middle ear, colds.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE OTOVOWEN[®]

Do not take Otovowen[®]

- if you are allergic to any of the active substances or any of the other ingredients of this medicine or Asteraceae. As a matter of principle, Otovowen[®] must not be used in case of progressive systemic diseases like tuberculosis, leukaemia and leukaemia-type diseases, inflammatory connective tissue diseases (collagenoses), auto-immune diseases, multiple sclerosis, AIDS, HIV-infection or other chronic viral diseases.

Warnings and precautions

Take special care with Otovowen®

- in case of fever, severe aches, head or neck pain, secretions from the ear and if symptoms persist over 2 days. If any of these symptoms develop, you must consult a doctor.
- in children under 2 years of age. Otovowen® should not be administered to children under 2 years of age without medical advice and should not be given in place of medicines prescribed by the doctor.

Other medicines and Otovowen®

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

There are no known interactions with other medicines.

Otovowen® with food and drink

The effect of a homeopathic medicine may be adversely influenced by generally detrimental lifestyle factors and by stimulants and luxury consumables.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

As there is no sufficiently documented experience with use during pregnancy and breast-feeding, Otovowen® should only be used during pregnancy and breast-feeding after consulting a doctor.

Driving and using machines

No special precautions are necessary.

Important information about some of the ingredients of Otovowen®

This medicine contains 53 vol.-% alcohol.

3. HOW TO TAKE OTOVOWEN®

Always take Otovowen® exactly as described in this leaflet. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by a doctor, the recommended dose is:

In **acute situations** take every half hour or every hour, up to a maximum of 12 x daily, in **chronic cases** take 1 – 3 x daily the following single doses:

Adults 12 – 15 drops

Children between 6 and 12 years 5 – 10 drops

Children under 6 years 4 – 7 drops

Infants under 1 year 2 – 4 drops (after seeking medical advice)

The single dose of 5 drops contains approximately 90 mg alcohol (see comments last page).

Infections affecting the nasopharyngeal area can easily spread to the middle ear particularly in children. Therefore Otovowen® should be taken early at the first signs of an infection of the upper respiratory tract. Treatment should be continued until all symptoms have subsided.

Duration of treatment

Otovowen[®] should not be used for more than 8 weeks.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Otovowen[®] can cause side effects, although not everybody gets them.

Possible side effects:

Hypersensitivity reactions may occur in isolated cases. Preparations containing echinacea have been observed to cause rash, itching, on rare occasions face swelling, breathlessness, dizziness and a fall in blood pressure.

If any of these symptoms develops, you should stop taking the medicine and consult your doctor.

Note:

When taking a homeopathic medicine, existing symptoms may worsen temporarily (initial worsening). If this happens to you, you should stop taking the medicine and consult your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the Bundesinstitut für Arzneimittel und Medizinprodukte [Federal Institute for Drugs and Medical Devices], Abt. Pharmakovigilanz [Pharmacovigilance Department], Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn, Website: <http://www.bfarm.de>. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE OTOVOWEN[®]

Keep this medicine out of the sight and reach of children.

Do not use Otovowen[®] after the expiry date which is stated on the label/carton after {exp.}. The expiry date refers to the last day of that month.

Storage conditions:

No special storage conditions are required for this medicine.

Shelf-life after first opening: 6 months.

6. OTHER INFORMATION**What Otovowen[®] contains:**

The active substances are:

10 ml contain:

Aconitum napellus Dil. D6 0.075 ml; Capsicum annuum Dil. D4 0.075 ml; Chamomilla recutita Ø 0.225 ml; Echinacea purpurea Ø 0.75 ml; Hydrargyrum bicyanatum Dil. D6 0.075 ml; Hydrastis canadensis Dil. D4 0.075 ml; Iodum Dil. D4 0.075 ml; Natrium tetraboracicum Dil. D4 0.075 ml; Sambucus nigra Ø 0.225 ml; Sanguinaria canadensis Ø 0.075 ml.

The other ingredient is: Ethanol 43 % (m/m).

1 ml is equivalent to 27 drops.

What Otovowen® looks like and contents of the pack

Otovowen® is a clear, yellow liquid.

Pack sizes: 30 ml and 50 ml mixture.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in July 2019.

Important patient information Middle ear inflammation

Dear patient,

Earaches are a typical sign of middle ear inflammation. Otitis media is among the most common childhood diseases. Otovowen® is an effective, plant-based homeopathic medicine, which has been used for over 50 years. It improves the symptoms of otitis media, and is very well tolerated. The drops are taken orally, so the affected ear does not need to be touched.

To ensure a rapid effect, it is important to take Otovowen® regularly and correctly.

Otovowen® are drops for oral use.

Please heed the dosing instructions on the first page.

To encourage rapid recovery:

- Drink lots of fluids so you activate the excretory organs.
- Do not force children to eat.
- In the event of fever, have plenty of bedrest, and perhaps apply calf wraps.

Naturally preserved by alcohol

Some parents are concerned about the alcohol content of herbal and homeopathic medicines. However, alcohol is important for the extraction and preservation of many natural active ingredients. It also encourages absorption through the mucous membranes.

Some foods also contain low doses of alcohol. For comparison: 5 drops Otovowen® contain less alcohol than half a glass of apple juice (100 ml).*

**Source: Kelber et al.: Ethanol in Herbal Medicinal Products for Children. Pharm. Ind. 70; No. 9, 1124-1127 (2008)*

TIP: To improve the taste of Otovowen®, you can take the drops with liquid (water, juice or tea).