

**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 annum Dil. D4; Chamomilla recutita Ø; Echinacea purpurea Ø; Hydrargyrum bicyanatum Dil. D6; Hydrastis canadensis Dil. D4; Iodum Dil. D4; Natrium tetraboracicum 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 contact a doctor if your symptoms worsen or do not improve after 2 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 medicinal product at inflammation of the middle ear.

Indications:

The indications derive from the homeopathic remedy pictures.

To these belong: Relief of the complaints at inflammation of the middle ear, cold.

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

Do not take Otovowen[®]

- if you are allergic to one of the active substances or other components or to composite. On theoretical grounds Otovowen[®] must not be used in case of progressive systemic diseases like tuberculosis, leukaemia and leukaemia-like diseases, inflammatory connective-tissue diseases (collagenoses), autoimmune diseases, multiple sclerosis, AIDS, HIV-infection or other chronic viral diseases.

Take special care with Otovowen[®]

- in case of fever, severe aches, head- or neckpain, secretion from the ear and if disorders persist over two days. In these cases you have to consult a doctor.
- of children under 2 years of age. Otovowen[®] should not be administered to children under 2 years of age without medical advice and does not replace drugs prescribed by the doctor.

Taking Otovowen® with other medicines:

Please 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.

Taking Otovowen® with food and drink:

The effect of a homeopathic medicine may be adversely influenced by generally harming factors in the way of living and by stimulating and luxury agents. When taking other medicines ask your doctor.

Pregnancy and breast-feeding:

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

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

Driving and using machines:

There are no special precautions 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 according to this leaflet. You should check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed, the usual dose is:

In **acute situations** take every half to full hour, at maximum 12 x daily, in **chronic cases** take 1 – 3 x daily following single doses:

Adults 12 – 15 drops;

Children between 6 and 12 years 5 – 10 drops;

Children to 6 years 4 – 7 drops;

Infants to 1 year according to medical advice 2 – 4 drops.

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

Infects of the nasopharyngeal zone can easily expand to the middle ear particularly at children. Otovowen® should therefore be taken early at the first signs of an infection of the upper respiratory tract. The therapy should be continued until all symptoms are decayed.

Duration of use:

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

If you have any further questions on the use of this product, 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:

In single cases hypersensitivity reactions may occur. For drugs containing preparations of echinacea rash, itching, rarely face swelling, breathlessness, vertigo and decrease in blood pressure were observed. In these cases you should stop taking the medicine and consult your doctor.

Note:

When taking a homeopathic medicine the initial symptoms may worsen temporarily (initial worsening). In that case 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, Abt. Pharmakovigilanz, 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 out of the reach and sight of children!**

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

Storage conditions:

For this medicine no special storage conditions are required.

Shelf-life after first opening: 6 months.

6. FURTHER INFORMATION**What Otovowen® contains:**

The active substances are:

10 ml contain:

Aconitum napellus Dil. D6 0,075 ml; Capsicum annum 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 approved in June 2014.

Important patient information!

Middle ear inflammation

Dear patient!

Earaches are a typical sign of a middle ear inflammation. Otitis media belongs to the most common childhood diseases. Otovowen[®] is an effective homeopathic medicine based on plants, which was used over more than 50 years. It improves the symptoms of otitis media, and is very well tolerated. The drops are orally taken, so the aching ear has not to be touched.

For a rapid effect it is important to take Otovowen[®] regularly and correctly!

Otovowen[®] are drops for oral use!

Please mind dosing instruction, see point 3!

So you can support the recovery:

- Drink enough to activate the excretory organs.
- Do not force children to eat.
- In case of fever keep bedrest, maybe leg compresses.

Naturally preserved by alcohol

Some parents are concerned about the alcohol content of herbal and homeopathic medicines. Alcohol is important for the production and preservation of many natural ingredients. It also supports the uptake through the mucous membranes. Also foods partly possess 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).