

Instructions for Use

This medical device and Instructions for Use are intended for use by a lay person.

Read the instruction for use before starting the treatment with Otovent®. Otovent® is for single-person use only.

Device Description

Otovent® is a nasal balloon device for autoinflation of the Eustachian tube to equalize negative middle ear pressure. Otovent® consists of two parts, a latex balloon and a polypropylene nose piece, which are connected before use. It is a non-sterile, reusable device. Packaging contains balloon/ balloons, nose piece and instructions for use. Some articles also contain a storage unit.

Otovent® Balloons are spare balloons to be used together with the nose piece provided with Otovent®. Otovent® Balloons are available in some markets.

Intended purpose

Otovent® is intended for treatment of negative pressure in the middle ear.

Who can use Otovent®?

Otovent® can be used by adults and in children aged 3 years and up. The treatment of children should always be supervised by an adult.

How does Otovent® work?

Otovent® helps equalizing the pressure in the middle ear when a balloon is inflated from the nose using an autoinflation technique. Autoinflation using a nasal balloon increases the nasal pressure, allowing the Eustachian tube to be opened.

Clinical Benefits

Symptoms of negative pressure in the middle ear can be blocked ear, impaired hearing, pain/discomfort, sensation of heaviness or dizziness.

When the Eustachian tube is opened using the Otovent® autoinflation technique, the middle ear is ventilated, any effusion can be cleared, and symptom relief is achieved.

Negative middle ear pressure, if left untreated, may result in otitis media with effusion (OME), also known as secretory otitis or glue ear, with collection of fluid in the middle ear. Problems equalizing negative pressure can occur due to Eustachian tube dysfunction and may follow an upper respiratory tract infection, an episode of acute otitis media or in connection with e.g., flying, diving or pressure chamber treatment.

When shall Otovent® not be used?

Otovent® shall not be used during an episode of acute otitis media or upper respiratory tract infection.

Warnings and Precautions

The balloons contain latex. If you are allergic to latex or latex products consult your healthcare professional before use. If you experience any allergic symptoms, such as rash, itching, difficulty in breathing or swelling, stop treatment and consult your physician.

Choking Hazard – Product contains small parts. Keep out of reach of children. The treatment of children should always be supervised by an adult.

Never use toy balloons while performing the Otovent® treatment. Only Otovent® Balloons should be used with CE marked Otovent® autoinflation medical devices.

If you suffer from frequent minor nosebleeds, any manipulation of the nose e.g., nose-blowing or balloon inflation, may provoke nosebleed. This condition is usually harmless.

If you have had sinus surgery, consult your physician before using Otovent®. Usage of Otovent® after having sinus surgery may increase risk of pneumocephalus.

If you experience perforated eardrum, severe headache, severe dizziness, sensitivity to light, and/or nausea in connection with using Otovent®, immediately stop treatment and consult your physician.

Some patients may experience discomfort in the ear during inflation. This initial sensation will decrease during the next inflation and is an indication that the procedure is working correctly.

Side Effects

Temporary pain in the ear and headache, dizziness, nose bleeds.

How to use Otovent®

For otitis media with effusion (glue ear)

During the first treatment week, Otovent® should be used at least three times a day (morning, noon, evening) with one inflation in each nostril at each occasion. After one week, Otovent® should be used at least twice a day (morning and evening). The treatment may continue for more than one month and maximal clinical effect may take several months. Consult your healthcare professional after 2-3 weeks to decide if the treatment should be continued.

For symptom relief after flying, diving or pressure chamber treatment

For use in connection with flying, Otovent® should be used 3-4 times as soon as the descent begins. If symptoms persist, treatment may continue after landing. Otovent® can be used several times before/after diving or during/after hyperbaric pressure treatment for symptom relief.

Step-by-step instructions

The nosepiece should be clean.

1. Connect the balloon to the flat end of the nose piece.
2. Hold the ball-shaped part of the nose piece firmly against your left nostril with your left hand. Compress your right nostril, using your right index finger.
3. Inhale deeply through your mouth, then close your mouth and inflate the balloon by blowing through your left nostril until the balloon is the size of a grapefruit (10-12 cm).
4. Still with the inflated balloon tight to the left nostril, perform some swallowing maneuvers.
5. Repeat the procedure through your right nostril.

It may take some practice to learn how to use Otovent®. A slight pre-stretch of the balloon before the first use may facilitate inflation.

Maintenance

Clean the nose piece with mild detergent after use. Rinse the nose piece with clean water. Discard the balloon when it has been used 20 times.

Storage and Disposal

When not in use, protect the nose piece and the balloons against light.

Disposal should be made according to local environmental procedures.

Notice to user

Any serious incident that has occurred in relation to the device should be reported to Circius Pharma AB and the local competent authority of your state.