

## INSTRUCTIONS FOR USE

### Short product description

Antinitus® is a method for relieving discomfort from tinnitus, developed and produced in Sweden after many years of research and studies. Antinitus® is easy to use, with a painless application process. Antinitus® is made with materials that are gentle on the skin.

Tinnitus is a common problem that affects approximately ten to fifteen percent of the population. Tinnitus is a sensation of sound in one or both ears, or inside the head, in the absence of a corresponding external sound source.

Read the instructions carefully before using Antinitus®. If you have questions or concerns regarding your condition, you should consult your health care provider.

### CONTENT

1. What does a package of Antinitus® contain?
2. What is Antinitus® used for?
3. How does Antinitus® work?
4. Warnings and precautions
5. How is Antinitus® used?
6. Storage
7. Contact details
8. Application

#### **1. What does a package of Antinitus® contain?**

The package contains an inner box of 21 Antinitus patches® and instructions for use.

#### **2. What is Antinitus® used for?**

Antinitus® is used for relieving discomfort from tinnitus in **adults**. Antinitus patches® are a disposable product that must be replaced every day to achieve the best result.

#### **3. How does Antinitus® work?**

Antinitus® is a patch designed to reduce discomfort from tinnitus. The patch contains a unique raster/lens that creates an organised signal, which is expected to, directly or indirectly, regulate nerve functions in the auditory system to relieve discomfort from tinnitus.

Clinical studies and clinical experience show that Antinitus® can relieve the symptoms of tinnitus and that Antinitus® is very safe to use.

#### 4. Warnings and precautions

– If you suffer from tinnitus and unilateral hearing impairment (not the same level of hearing in both ears) with no known cause, or if you have pulsating tinnitus (like your pulse) or other ear symptoms, you should consult a physician before using Antinitus®.

– Antinitus® is a method for the relief of discomfort from tinnitus only.

– Antinitus® has not been studied in children and must therefore not be used for the relief of discomfort from tinnitus in children below the age of 18 unless prescribed by a physician.

– Antinitus® must not be used on damaged or irritated skin.

– If the skin becomes irritated you must discontinue the use of Antinitus® until the irritation has ceased. Treatment can be resumed as soon as the irritation has disappeared.

– If you experience an allergic reaction while using Antinitus® you must discontinue your use of the product and contact a physician.

– Antinitus® must not be used in combination with other tinnitus treatments unless prescribed by a physician.

– Antinitus® has no known effect on pharmaceutical drugs and can be used unless a physician has advised against it.

– Antinitus® has no known effect on hearing aids and can be used unless a physician has advised against it.

– Tinnitus symptoms may increase at the start of treatment, but this normally subsides after a few days.

– The use of Antinitus® is not recommended during pregnancy or nursing as no clinical studies have been conducted on this group.

– The effect of Antinitus® varies between individuals and it does not work for everyone.

– Do not use damaged Antinitus patches® or patches from a damaged package.

– The patches must not be reused.

– Must be kept out of reach of children.

#### *General information:*

– Antinitus® is a CE marked medical device.

## 5. How is Antinitus® used?

Apply the Antinitus patch® as described in the APPLICATION instructions. The patch must be replaced daily and worn for 24 hours. Do not use the Antinitus patch® for more than 21 consecutive days. Use only one patch at a time.

Apply the patch behind the ear in which you are experiencing tinnitus symptoms. If you have problems with both ears, you apply the patch behind the ear with the more serious symptoms. It is a good idea to replace the patch at around the same time everyday, e.g. after breakfast or after taking a shower, to help you remember to apply a new Antinitus patch®.

Once the patch has been opened it must be used immediately and replaced daily. The patch must not be reused and the effect cannot be guaranteed. Since tinnitus manifests itself differently in different people, the effect may vary. One experience from the studies is that the alleviating effects increase after the completion of the treatment.

You can live normally during the treatment and do not have to make any changes with regard to, for example, exercise, spending time out or indoors or the way you wear your hair.

### *Recurring tinnitus*

If the tinnitus symptoms increase/return after a round of treatment, the use of Antinitus® may be resumed four weeks after the end of the previous treatment cycle.

## 6. Storage

Store the patches in their box in a dry place at room temperature (18 °C to 25 °C). Keep away from direct sunlight. The expiration date is printed on the package. Once the patch has been opened it must be used immediately and replaced daily. Used Antinitus patches® can be discarded with normal household waste or as combustible waste. The box and the instructions for use can be separated as waste paper after the treatment period.

## 7. Contact details

Manufacturer:  
Antinitus AB  
Nybrogatan 39  
SE-114 39 Stockholm  
Sweden

For additional information, please visit [www.antinitus.com](http://www.antinitus.com)

## APPLICATION

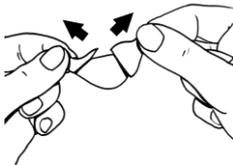
1. Apply the Antinitus patch<sup>®</sup> behind the ear in which you are experiencing tinnitus symptoms. If you have problems with both ears, you apply the patch behind the ear with the more serious symptoms. Carefully clean the skin behind the ear with soap and water. Dry thoroughly before applying the Antinitus patch<sup>®</sup> as it will not stick to oily or damp skin.



2. Check the package before use to ensure that the patch is not damaged. Open as illustrated.



3. Peel off the protective film from the back of the patch as illustrated.



4. Keep long, flowing hair out of the way with one hand and apply the Antinitus patch<sup>®</sup> behind the ear with the other, as illustrated. Press carefully on the patch to ensure that it sticks well to the skin.



5. Clean the skin with soap and water after removing the Antinitus patch<sup>®</sup>. Follow the instructions in figures 1–4 when applying a new Antinitus patch<sup>®</sup>.

