This internally generated noise can be debilitating, and there are reported cases of suicidal tendencies in some sufferers. Patients may describe the sound (or sounds) as ringing, humming, hissing, or even “a choir of angels singing on Easter Sunday morning.”

In most cases tinnitus is cochlear in origin; however, those patients who do not also have hearing loss need to be further evaluated. Is the tinnitus an adverse side effect of a particular pharmaceutical they are taking for another medical condition? A comprehensive list of pharmaceuticals with auditory/perceptual side effects can be found online at www.earserv.com/drugs. Additional information about adverse herbal and nutritional/dietary supplement side effects can be found in DiSogra (2003, 2012).

Although tinnitus may have been a reported side effect during a drug’s clinical trials (prior to approval by the U.S. Food and Drug Administration [FDA]), the incidence might be extremely low. Therefore it is critical to learn when the drug was first introduced and when the tinnitus was first noticed. If the patient cannot specifically identify a drug’s start date, a phone call to the patient’s pharmacy solves the problem (DiSogra, 2001, 2004, 2008).

Sometimes, rather than consult their primary care physicians, otologists, or audiologists, tinnitus sufferers self-medicate in hopes of managing or curing their tinnitus. They may see tinnitus relief products on television, radio, or print media or turn to the Internet to obtain information about tinnitus relief. And that’s when the trouble begins.

**Product Analysis**
The Internet was the starting point for this study on over-the-counter tinnitus relief products because this is where a person suffering from tinnitus will usually
Over-the-Counter Tinnitus Relief Products: Why Reading the Label Is Important

BY ROBERT M. DISOGRA

Rather than consult a professional, tinnitus sufferers may self-medicate in hopes of managing or curing their tinnitus. But while more than 50 over-the-counter products are available that claim some form of relief or a cure for tinnitus, none of them are approved by the U.S. Food and Drug Administration.

start a search for information. First, a Google search was completed using the following key words: tinnitus, tinnitus product, tinnitus cure, tinnitus relief, tinnitus help, tinnitus treatment, and tinnitus remedy.

Over 50 products (herbal supplements, vitamins, homeopathic remedies, and mechanical devices) were identified (SIDEBAR), all claiming to either temporarily or permanently relieve tinnitus and all available without a prescription. Folklore, tradition, and usually nonscientifically evaluated ingredients are mixed into pills or powders with dosages usually reported in milligrams and no minimum daily values established. The cost is anywhere from a few dollars to over $40 for a one-month supply (a three-month minimum supply is usually recommended). And no guarantees are offered.

There were typically no sources to support the claims about tinnitus relief made by the manufacturers or distributors of the products. It was not unusual to read statements such as “helps reduce ear noises” or “studies have shown that XYZ can reduce ringing noises in the ear.” The challenge was to track down those studies, which, for the most part, were not in any peer-reviewed journal. According to www.daveshealingnotes.com, for example, “High pitched noises need to be dealt with [with] kidney remedies. Low-pitched sounds are best treated with liver remedies.” One wonders, Who is Dave? The vast majority of product sites cited no peer-reviewed or scientific sources about efficacy or safety. In some instances, more information about the ingredients was found on Amazon.

Unless otherwise indicated, all the herbs, minerals, compounds, juices, oils, creams, and transdermal products listed have not been evaluated by the FDA for safety and efficacy. Claims about the safety and efficacy of herbals/nutritional supplements do not have to be proven because the FDA classifies them as food. Consequently, the manufacturer does not have to go through the scientific scrutiny that a pharmaceutical must go through prior to FDA approval. All the product’s manufacturer needs to do is print the Dietary Supplement Health and Education Act of 1994 (DSHEA) disclaimer on the label: “This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.”
OTC Tinnitus Relief Products

Accu-Hear
Arches Tinnitus Formula
Bio-Ear
Calm Tinnitus Ear Drops
Clarity2
Clear Tinnitus
Deafness Pill
Ear Aid
Ear Perfect
Ear Ringing
EARS – BLF
Er Long Zuo Ci Wan
Lipoflavonoid Plus
Lipoflavovit
Liu Wei Di Huang Wan
Mason Natural Advanced
Memory Recall
NeuroZeil
Ear Health Formula
Nu-Tinnitus
Polyflavonoid
Quietus
Reconnect
Ring Free
Ring No More
Ring Relief Caplets
Ring Relief Drops
Ring Relief Tablets
Ring Stop Capsules
Ring Stop Ear Drops
Shen Jing Shuai Ruo Wan
SinusWars16
Sonavil/Lucid Head*
Stabelite
T-Gone
TinnaRex Ear Drops
TinniSpray
Tinnitus
Tinnitus Control
Tinnitus Miracle
Tinnitus Relief (HomeoCare)
Tinnitus Relief (Homeolab)
Tinnitus Relief (King Bio)
Tinnitus Relief (MagniLife)
Tinnitus Relief (Serenity)
Tinnitus Solution*
TinnitusDX
Tinntutab
Tinusol
X-Tinnitus
Zhi Bai Di Huang Wan

*Product no longer available.

Product Ingredient Analysis

APPENDIX A contains an alphabetical list of each ingredient in the products identified in this study—228 ingredients in total, the most comprehensive list of its type (click here to access APPENDIX A, go to www.audiology.org and search key words “tinnitus relief products”). The purpose of this list, which also contains a description of each ingredient and, when available, claims regarding its treatment of tinnitus, is to guide the health-care professional when helping a patient to make informed decisions about the use of tinnitus relief products.

Peer-reviewed research in English exists for just 24 of the 228 ingredients. Double-blind, clinical studies using acceptable research methods are lacking. Most sources are more than 20 years old, some as much as 60 years old.

Folklore, tradition, and usually nonscientifically evaluated ingredients are mixed into pills or powders, available without a prescription and claiming to relieve tinnitus.

Resources

The Web sites used as primary information sources for this study included those of the FDA, the National Institutes of Health, and the National Library of Medicine (and its databases Medline Plus and PubMed) as well as university medical school sites, Amazon, Wikipedia, manufacturer sites, distributor sites (for Chinese herbs), commercial retail sites, sites devoted to traditional Chinese medicine, and other sites containing information by uncredentialed individuals or having no advisory board (e.g., www.soyouwanna.com, www.vegrecipes4u.com, www.wisegeek.com).

The following books were used in identifying and providing further information on product ingredients: PDR for Herbal Medicines, 4th edition (2007), PDR for Nutritional Supplements, 2nd edition (2008), and PDR for Nonprescription Drugs, Dietary Supplements, and Herbs (2011).
“Contact Us”
Twenty-five manufacturers of OTC tinnitus relief products were contacted in March 2013. The author requested the following information:

1. Name and credentials of the senior investigator, researcher, nutritionist, herbalist, or advisory board members who made the decision to include the ingredients listed in your product

2. A reference list of published articles showing the efficacy and safety of each ingredient in your product as it pertains to tinnitus

3. Any consumer/medical reports of the long-term effects of continuous use of this product

Two companies responded. One reported that they were “too busy” to answer my inquiry, and the other company informed me that they had discontinued their tinnitus relief product “because it just didn’t work.”

“But It Helps!”
Despite having no FDA-approved, evidence-based research with a definitive statement about tinnitus relief, you may encounter a patient who has derived benefit from any one of the available OTC products purporting to relieve tinnitus (to any degree). Congratulate the patient on finding some relief, but keep in mind that it is not our responsibility to advise the patient to discontinue use of a tinnitus relief product. However, it is our responsibility to inform them that, with no real scientific evidence, they may be throwing their money away on an unproven product.

Some Caution Should Be Observed
Some of the ingredients in the products claiming to relieve tinnitus should be avoided by children and patients with cardiac disease (tinnitus is a side effect of several cardiac drugs), and pregnant women should read the label carefully. Some ingredients appear on the FDA’s poisonous plants list. And some of the products claiming to relieve tinnitus contain quinine, which is known...
to cause tinnitus. Therefore, when your patients ask for advice on OTC tinnitus relief products (they usually will bring in an ad from a magazine or newspaper) or the latest "cure" for tinnitus, it is the author's intention that you will use the information in this article to counsel them and caution them that none of these products are approved or endorsed by the FDA and that they are not intended to diagnose, treat, cure, or prevent any disease.

Suggested Treatment
It is suggested that the treatment of patients with tinnitus consist of the following:

1. A detailed case history, during which the patient is asked whether he or she is using any OTC products for tinnitus

2. A review of the patient's current medications and their side effects

3. A review of the patient's diet and daily nutrition regimen (including dietary supplements, if taken)

4. Establishment of a timeline from the start of any prescription to tinnitus awareness

5. An otologic examination to establish a cause

6. Routine blood work

7. A comprehensive audiological evaluation including otoacoustic emissions

Claims about the safety and efficacy of herbals/nutritional supplements do not have to be proven because the FDA classifies them as food.
8. Completion of the Tinnitus Handicap Inventory and/or other self-assessment tool

Until safety and efficacy have been demonstrated in scientific studies using recognized research methods on a large sampling of the population, the use of OTC tinnitus relief products is strictly at the patient’s discretion and not recommended.

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References


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