

VERTIGOHEEL[®] FACT SHEET

- VERTIGOHEEL[®] is officially classified as a homeopathic combination medication available by prescription only and is indicated for the treatment of vertigo, other related imbalance disorders, and related symptoms such as nausea. VERTIGOHEEL[®] is also indicated for the prevention and treatment of motion sickness.
- VERTIGOHEEL[®] is a formulation of the following botanical, zoological, and mineral substances:
 1. Botanical:
 - Conium maculatum (umbelliferae)
 - Cocculus indicus (menispermaceae)
 2. Zoological:
 - Ambra grisea (ambergris)
 3. Mineral:
 - Petroleum (purified mineral oil)
- The exact mechanism of action of VERTIGOHEEL[®] is not fully understood. However, studies suggest that VERTIGOHEEL[®] is effective in treating vertigo and nausea due in part to its ability to stimulate the central nervous system. VERTIGOHEEL[®] activates the vestibular regulatory systems located in the brainstem area, which may facilitate more accurate communication between the peripheral vestibular system and the brain.
- Adverse effects with VERTIGOHEEL[®] are extremely rare; it exhibits no known adverse renal, hepatic, cardiovascular, gastrointestinal or central nervous system effects and is generally well tolerated, even during long term administration.
- VERTIGOHEEL[®] is contraindicated in patients with known hypersensitivity to it or any of its ingredients. VERTIGOHEEL[®] is not known to interact with other medications or laboratory tests.
- An extensive, randomized, double-blind, controlled clinical trial demonstrated that VERTIGOHEEL[®] is as effective as betahistine (Serc[®], Sanofi Winthrop) in reducing the frequency, duration, and intensity of vertigo attacks. Betahistine is a drug that is routinely prescribed for the treatment of vertigo in Europe and other regions of the world, especially vertigo associated with Meniere's disease.
- VERTIGOHEEL[®] is available in bottles of 100 tablets, Oral Drops in 50 ml bottles, and Oral Liquid in Vials, 1.1 ml packs of 10. All of the VERTIGOHEEL[®] ingredients are included in the Homeopathic Pharmacopeia of the United States (HPUS), and the drug is manufactured and marketed in the U.S. according to the Food and Drug Administration's Code of Federal Regulations (including Good Manufacturing Practices) and Compliance Policy Guides - Conditions Under Which Homeopathic Drugs May be Marked.

VERTIGO FACT SHEET

- Vertigo is a false sensation of movement of one's self or of one's surroundings.¹
- Medical care for patients with balance, or vestibular, disorders has been estimated to cost the U.S. economy more than \$1 billion annually. Such disorders are among the 25 most common reasons for doctor visits with U.S. physicians reporting more than five million related visits per year.²
- Vertigo sufferers commonly experience other related symptoms such as diaphoresis (excessive perspiration), blurred vision or oscillopsia (a false visual perception that one's surroundings are moving), nausea and/or vomiting, anxiety, and fear. These symptoms may be experienced separately or in combination, can strike at any age, and can affect people from all walks of life.^{2,4}
- Vertigo symptoms are often linked to problems of the peripheral vestibular apparatus within the inner ear, such as ear infections and structural deformities, or central nervous system (CNS) conditions such as head trauma, migraine, whiplash or brain tumors. In addition, stress/fatigue, high doses or long-term use of certain antibiotics, and advanced age are believed to contribute to the development of vertigo.^{2,3}
- Vertigo symptoms are often associated with four conditions: benign paroxysmal positional vertigo (BPPV), Meniere's disease, perilymph fistula, and vestibular neuritis/labyrinthitis; other causes include injuries to the head and neck and psychiatric conditions.
- BPPV causes vertigo due to displaced debris within the inner ear. Vertigo in Meniere's disease is caused by the endolymph mixing with the perilymph of the inner ear.
- Perilymph fistula causes vertigo due to a tear or defect in the membranes that separate the inner ear from the middle ear. The vertigo associated with vestibular neuritis/labyrinthitis is caused by infections of the peripheral vestibular system.
- Diagnosis of these diseases is based on the patient's medical history, a complete physical examination, and the results of vestibular and auditory tests. Once diagnosed, a patient may be placed on a special diet and prescribed a series of physical rehabilitation techniques, drug therapies or, if such treatments are unsuccessful, surgical procedures.⁵
- Although several medications in the U. S. are used to treat vertigo, no conventional drug has been proven effective for its treatment. In Europe, the most commonly prescribed anti-vertigo medication is the histamine analogue, betahistine (Serc[®], Sanofi Winthrop), which relieves vertigo symptoms by improving circulation in the microvasculature of the inner ear.
- VERTIGOHEEL[®], a prescription homeopathic medication, is specifically indicated for the treatment of vertigo and other related imbalance disorders. Although its exact mechanism of action is not fully understood, VERTIGOHEEL[®] stimulates the vestibular regulatory systems located in the brainstem and increases neuropathway activity. This increased activity may facilitate more accurate communication between the vestibular system and the brain.

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Backgrounder

UNDERSTANDING VERTIGO

Vertigo is a false sensation of movement, either of one's self or one's surroundings.¹ It may exist as an isolated symptom or it may be associated with other conditions such as ear infections, migraine or psychiatric conditions.

Medical care for patients with balance, or vestibular, disorders has been estimated to cost the U.S. economy more than \$1 billion annually.² In addition, according to the National Ambulatory Medical Care Survey conducted in 1991, vestibular disorders are among the 25 most common reasons for doctor visits, with U.S. physicians reporting more than five million related visits per year.²

Vertigo - a Vestibular Disorder

It is important to recognize that patients complaining of "dizziness" and/or "vertigo" could be experiencing these symptoms separately, or in combination, but they do not mean the same thing. Vertigo may be considered a subset of the larger category of dizziness symptoms. It is a sensation of motion - either horizontally or vertically - when one is stationary. Dizziness denotes less specific symptoms such as a lack of balance and lightheadedness.³

The inner ear can be roughly divided into two parts: the peripheral vestibular apparatus (versus the central vestibular structures of the brain) and the cochlea. The cochlea is involved primarily with hearing. The peripheral vestibular apparatus functions in association with the central vestibular structures to coordinate the numerous neurological and structural systems that maintain proper equilibrium. Disturbances of these systems in the form of vestibular disorders cause inaccurate and confusing information about body movement, resulting in vertigo or dizziness.^{1,4}

Vestibular disorders, such as vertigo, can strike at any age and can affect people from all walks of life.² Estimates suggest that approximately two million adults in the U.S. frequently

experience dizziness or lack of balance. In fact, one-third of those who participated in a study of people age 65-75 experienced dizziness and imbalance.⁵

People experiencing vertigo commonly exhibit other related symptoms including:

- diaphoresis (excessive perspiration)
- blurred vision or oscillopsia (a false visual perception that the surroundings are moving)
- nausea and/or vomiting
- anxiety and fear

Causes of vertigo can be linked to problems of the peripheral vestibular apparatus within the inner ear, such as ear infections and structural deformities. Central nervous system (CNS) conditions, such as head trauma, migraine, whiplash, stroke, brain tumors, or conditions resulting in reduced blood flow to the inner ear or brain, can also cause vertigo. In addition, factors such as stress, fatigue, high doses or long-term use of certain antibiotics, and advanced age are also believed to contribute to the development of vertigo.²

People experiencing symptoms should avoid caffeine, smoking, and alcohol consumption, factors known to increase the frequency of vertigo and trigger its onset.⁵

Equilibrium and Mechanisms of the Ear

Equilibrium is defined as a state of balance⁶ which is maintained by the constant interactions of three systems: the peripheral and central vestibular systems detect head positioning and movement; the ocular system controls the eye and its structures; and the proprioceptive system conveys information about body position and muscle contraction.¹

A number of mechanisms are involved in the processing of movement by the brain. The vestibular nerve transmits sensory information received from the semicircular canals in the inner ear to vestibular nuclei of the brainstem. Central vestibular signals are then relayed to the vestibular cortex and monitored, as well as modulated, by the cerebellum, which is involved in other systems of motor coordination beyond the vestibular system. Each ear contains three semicircular canals that detect angular acceleration of the head in three dimensions. Each canal is filled with fluid called endolymph, which responds to movement. As the endolymph shifts in response to the slightest head movement, it deflects a membrane which lines the semicircular

canals. This deflection registers with the vestibular nerve which instantaneously sends impulses to the cerebellum. A defect in any of these systems may result in dysequilibrium.³

Vertigo and Vertigo-related Conditions

A common cause of vertigo is referred to as benign paroxysmal positional vertigo (BPPV). However, vertigo symptoms are often associated with other conditions, most notably, Meniere's disease, perilymph fistula, vestibular neuronitis/labyrinthitis, migraine, drug toxicities, and CNS disorders.

The proper diagnosis of these diseases is based on a patient's medical history, complete physical examination, and the results of vestibular and auditory tests. A physician may wish to conduct electronystagmography (ENG) or caloric testing to detect nystagmus – a drift of both eyes in the same direction followed by rapid movement in the opposite direction. ENG is performed in a darkened room where warm and cool air is introduced into the ear canal. Eye movements are then recorded to test balance.⁷ A physician could request magnetic resonance imaging (MRI) of the brain if a stroke or tumor is suspected. An audiogram which records the intensity by which an individual hears different frequencies of sound may be needed to distinguish between vestibular neuronitis and other conditions of the inner ear.^{1,8} Computerized Dynamic Posturography (CDP) is often used at specialized medical centers for evaluating balance problems. This device utilizes a moveable foot plate and measures the patients' postural responses to a variety of positions and movements. Physicians may also perform blood tests to detect diabetes, thyroid disorders, Lyme disease, and syphilis, conditions known to cause balance disorders.⁸

Benign paroxysmal positional vertigo (BPPV), also known as benign positional vertigo (BPV), causes dizziness and vertigo due to displaced debris, or otoconia, which have collected within the semicircular canals of the inner ear.⁹ Derived from a structure in the ear called the utricle, these otoconia are small crystals of calcium carbonate that, when displaced, can inaccurately stimulate the vestibular nerve.⁷

Although many of the causes of BPPV have not been specifically identified, head injury is a common cause for people under the age of 50. Although approximately 50 percent of all

BPPV cases are considered “idiopathic” in that there is no known reason for their occurrence,⁹ many of these cases may be due to a gradual loosening of the otolithic calcium carbonate crystals of the inner ear as part of the aging process.

The symptoms of BPPV, in addition to vertigo, include lightheadedness, dizziness, and nausea frequently brought on by a sudden change in head position. An intermittent symptom pattern is common, stopping for a few weeks, then returning. The most common symptom of BPPV is matutinal vertigo, in which the patient experiences a brief, intense sense of spinning when lying back in bed or when turning over during sleep. If a BPPV patient suddenly feels unsteady when looking up from an upright position, they are experiencing what is termed “top shelf vertigo.”⁹

A condition closely associated with vertigo is **Meniere's disease**, sometimes called endolymphatic hydrops. Meniere's disease is associated with other symptoms in addition to vertigo, including tinnitus (a ringing or rushing sound), pain or pressure in the ears, and varying degrees of hearing loss.¹⁰

Vertigo symptoms in Meniere's disease are probably caused by the mixture of two fluids in the ear - the endolymph and perilymph. An increase in the amount of endolymph within the inner ear - specifically within the labyrinth - causes the membranous labyrinth to expand and possibly rupture. When this occurs, the endolymph mixes with the perilymph - fluid found between the membranous labyrinth and the inner ear - resulting in vertigo symptoms.¹¹ Although the condition most commonly affects only one ear, both ears are affected in 15 percent of patients.¹⁰

Scientists are unclear as to the exact cause of Meniere's disease, although autoimmune disorders, environmental changes, and viral infections might play a role. Whatever the cause, Meniere's disease symptoms typically begin between 20 to 50 years of age and affect men and women equally.⁵

A **perilymph fistula** can also cause vertigo symptoms. This is a tear or defect in the membranes that separate the inner ear from the middle ear, often caused by moderate to severe changes in ambient pressure (e.g., air pressure changes while flying or water pressure changes while diving), head trauma, or whiplash injuries. Normally, air pressure changes in the middle ear do not affect the inner ear. However, when a tear or defect between the two occurs, middle

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ear pressure will directly affect the inner ear, inappropriately stimulating the balance and/or hearing structures. Symptoms of perilymph fistula include dizziness, vertigo, imbalance, nausea, and vomiting.

Another condition associated with vertigo is **vestibular neuronitis/labyrinthitis** which is often caused by infections of the peripheral vestibular system. In vestibular neuronitis, infections are usually viral and hearing is unaffected. In labyrinthitis, however, the infections are usually caused by either bacteria or viruses, and hearing is typically affected. Vestibular neuronitis/labyrinthitis accounts for about five percent of all dizziness complaints and approximately half of all sufferers experience a single attack with further episodes occurring over a period of months to years.^{4,8} Symptoms are often worsened or exacerbated by sudden head movements.⁹

In addition to these conditions, other significant causes of vertigo include injuries to the head and neck - called post-traumatic vertigo. Head trauma (e.g., concussion), bleeding in the ear, utricular injury, and cerebellar and brainstem disturbances, commonly cause post-traumatic Meniere's syndrome, positional vertigo and/or post-traumatic migraine. Neck injury may result in cervical vertigo in which dizziness occurs with neck movement.¹² Psychiatric disorders, including depression, anxiety, and alcohol dependency, also can cause patients to experience symptoms of vertigo.¹³

Treatment

There is no consensus among medical authorities in the U.S. regarding the specific treatment of vertigo. Therapy often consists of medication, physical therapy, and diet, administered singularly or in combination. If these treatments are unsuccessful and the vertigo severe, surgery is occasionally considered.

One of the first steps in treating a patient suffering from a vestibular disorder is to determine whether the patient is suffering from vertigo or another specific type of dizziness such as lightheadedness, dysequilibrium, or anxiety-related dizziness. It is important to distinguish between the two in order to develop an effective treatment strategy. Once diagnosed, patients may undergo a series of physical rehabilitation techniques, drug therapies, or surgical procedures.

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Physical Rehabilitation

When treating patients suffering from BPPV, physical rehabilitation involving positioning of the head has shown to be helpful. The **Epley & Semont maneuvers** and the **Brandt-Doroff exercises** move displaced otoconia out of the posterior canal to a less sensitive location within the inner ear.⁹ These methods also help the CNS adapt to abnormal vestibular signals; an adaptation process that many conventional anti-dizziness medications are known to impair. The Semont maneuver, or “liberatory” maneuver, is preferred in Europe and involves rapidly positioning the patient’s head by having the patient lie on one side and then lie on the other. The Epley maneuver, which is used more often in the United States, is also known as particle repositioning, canalith repositioning, and modified liberatory maneuver. The Epley maneuver involves positioning a patient’s head in four basic movements, holding each position for about 30 seconds. Although the vertigo has a recurrence rate of about 30 percent after these exercises have been implemented, the maneuvers have been proven effective in about 80 percent of all BPPV patients.⁹

If vertigo recurs, physicians may wish to administer a second session of these maneuvers or proceed to the **Brandt-Daroff exercises** which are successful in treating 95 percent of all BPPV cases. In the Brandt-Daroff exercises, the patient sits in an upright position then lies on his/her side with the head angled upward half-way. This is followed by having the patient lie still for 30 seconds or until dizziness subsides. After returning to the sitting position for 30 seconds, the patient then moves to the opposite side and repeats the same movement. The exercises are performed five times per set at a rate of three sets per day for two weeks. Complete relief from symptoms is obtained in most patients after 30 sets or about 10 days. However, BPPV symptoms will recur within one year in about 30 percent of patients.⁹

These so-called canalith repositioning maneuvers are only effective with BPPV. When patients are diagnosed with Meniere’s disease, perilymph fistula, vestibular neuronitis/labyrinthitis, or CNS vertigo, pharmaceutical therapies are often employed. Vestibular rehabilitation can also be employed for other forms of dizziness and impaired equilibrium. Patients are typically instructed in a series of specific exercises that stimulate vestibular, proprioceptive, and visual systems to enhance the process of adaptation and to gradually diminish conflicting sensory signals.

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Pharmaceutical Therapies

Physicians can prescribe a number of different medications to control vertigo. In Europe, the most commonly prescribed anti-vertigo medication is the histamine analogue called betahistine. Betahistine relieves vertigo symptoms by improving circulation in the microvasculature of the inner ear which leads to a pressure reduction on the membranous labyrinth. In a European study conducted in 1985 by Fischer and van Elferen, betahistine proved to be effective for the treatment of vertigo, including controlling the duration and intensity of attacks, with more patients experiencing full symptom stoppage in the last month of treatment.¹⁴

While a number of medications in the U.S. are used, there is a lack of conventional pharmaceutical products proven effective for the treatment of vertigo. For example, although many physicians prescribe Antivert[®] (meclizine), the drug is classified by the FDA as only “possibly effective” in the management of vertigo.

On the other hand, a prescription homeopathic remedy, VERTIGOHEEL[®], has been indicated as effective in the treatment of vertigo as well as other related imbalance disorders. VERTIGOHEEL[®] appears to exert its therapeutic effect by stimulating the vestibular regulatory systems located in the brainstem and increasing neuropathway activity. This increased activity appears to facilitate more accurate communication between the vestibular system and the brain.

In a recent study published in *Archives of Otolaryngology - Head and Neck Surgery*, VERTIGOHEEL[®] was shown to be as effective as betahistine in reducing the frequency, duration, and severity of vertigo attacks. More than 70 percent of patients in the VERTIGOHEEL[®] and betahistine groups reported a significant improvement in quality of life. In addition, more than 90 percent of study patients in both the VERTIGOHEEL[®] and betahistine treatment groups exhibited “good” or “excellent” tolerability of the medications. Side effects reported by the VERTIGOHEEL[®] group included nausea, tremor of the hands, and headache. Side effects reported by the betahistine group included all of these symptoms as well as strong vertigo.¹⁵

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Other medications which are conventionally used for the treatment of vertigo are listed below. However, as stated earlier, none of these drugs are specifically indicated for the treatment of vertigo.

- *Diuretics*, such as hydrochlorothiazide, reduce vertigo symptoms by controlling the amount of endolymph within the semicircular canals.
- *Antihistamines* like Antivert[®]/Bonine[®] (meclizine) and Dramamine[®] (dimenhydrinate) may increase motion tolerance but must be administered prior to the onset of symptoms. This group of medications causes side effects such as drowsiness, dry mouth, blurred vision, and constipation. The Food and Drug Administration (FDA) has classified Antivert[®] as only “possibly effective” in the management of vertigo.
- *Antinauseants* are not necessarily prescribed to control the vertigo symptoms, but to control the nausea associated with vertigo attacks. These drugs, such as Compazine[®] (prochlorperazine), Phenergan[®] (promethazine) and Tigan[®] (trimethobenzamide), are very closely related to the antihistamines with similar side effect profiles.
- *Benzodiazepines* such as Valium[®] (diazepam) and Antivan[®] (lorazepam) suppress abnormal vestibular responses to inaccurate vestibular stimuli. Side effects include addiction, impaired memory, and increased risk of falling.¹⁶

Surgical Procedures

When physical therapy and medications are ineffective, surgical procedures often represent the patients' and physicians' last option for the treatment of vertigo. Depending on the nature and severity of the condition, conservative surgical procedures such as an endolymphatic shunt, also known as a decompression procedure, may be performed for Meniere's disease. Microvascular decompression of the vestibular nerve is considered when a blood vessel at the base of the brain is suspected to be compressing the vestibular nerve. In extreme cases, physicians may perform destructive procedures, including vestibular neurectomy or labyrinthectomy, that destroy the mechanism responsible for the vertigo symptoms.³

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The insertion of an endolymphatic shunt or a decompression procedure is an operation that drains excess fluid from the inner ear through an incision made in the bone section behind the ear or mastoid. A tube is then inserted to control the abnormal fluid pressure.¹⁷ This

operation usually preserves hearing and relief of vertigo symptoms is sustained in one-half to two-thirds of cases. Recovery time is comparably shorter than other procedures.⁷

Selective vestibular neurectomy is a destructive surgical procedure in which the vestibular nerve that maintains balance is severed and, therefore, can no longer send confusing messages to the brain.⁵ In most cases, vertigo attacks are eliminated permanently. However, there is a risk of lessened hearing or facial muscle control and older patients experience longer recovery times.⁷

When all other treatment methods fail, another destructive surgical procedure called a labyrinthectomy may be performed. This procedure involves the destruction and removal of the membranous labyrinth, the balance and hearing mechanism, and is an irreversible procedure. It is often successful in eliminating vertigo but results in a total loss of hearing in the operated ear and may cause other balance problems.¹¹

Conclusion

Differentiation between vertigo and other types of dizziness is crucial in the diagnosis and subsequent treatment of these symptoms. As knowledge of vertigo and its associated conditions advance, so do the available diagnostic and treatment methods. As a first course of action, patients experiencing dizziness and vertigo symptoms should consult a physician in order to develop an appropriate, individualized treatment program.

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