

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use WellMind™ Vertigo Tablets safely and effectively. See full prescribing information for WellMind™ Vertigo.

WellMind™ Vertigo Tablets, Oral Use Rx Only

-----INDICATIONS AND USAGE-----

WellMind™ Vertigo is a homeopathic drug indicated for the treatment of vertigo/dizziness of various origins; mild cognitive impairment (MCI) such as lack of concentration and forgetfulness. (1)

-----DOSAGE AND ADMINISTRATION-----

Allow tablets to dissolve completely in the mouth, do not swallow.

• Standard Dosage:

Adults and children 12 years and older:

3 tablets per day, taking 1 tablet every 4 to 6 hours. (2.2)

• Acute Dosage:

Adults and children 12 years and older:

1 tablet every ½ to 1 hour until symptoms lessen, then continue with standard dosage. Do not exceed 12 tablets in 24 hours. (2.3)

-----DOSAGE FORM AND STRENGTH-----

- 300 mg tablets each containing the active ingredients in the strengths listed under Description. (3)

-----CONTRAINDICATIONS-----

- WellMind™ Vertigo Tablets are contraindicated in patients with known hypersensitivity to WellMind™ Vertigo or any of its ingredients.
- Do not use during pregnancy or breastfeeding. (4)

-----WARNINGS AND PRECAUTIONS-----

- None (5)

-----ADVERSE REACTIONS-----

- No adverse events with a causal relationship to WellMind™ Vertigo tablets have been reported.
- **To report SUSPECTED ADVERSE REACTIONS, contact MediNatura. at 1.844.633.4628 or info@MediNatura.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

-----DRUG INTERACTIONS-----

- None known (7)

-----USE IN SPECIFIC POPULATIONS-----

- No studies have been conducted with WellMind™ Vertigo Tablets on pregnant or lactating women, children, or elderly. (8)

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* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 Indications and Usage

- 1.1** WellMind™ Vertigo Tablets are a homeopathic drug product indicated for the treatment of vertigo/dizziness of various origins; mild cognitive impairment (MCI) such as lack of concentration and forgetfulness.

2 Dosage and Administration

2.1 General Considerations

- The dosage schedules listed below can be used as a general guide for the administration of WellMind™ Vertigo Tablets.
- Allow tablets to dissolve completely in the mouth, do not swallow.

2.2 Standard Dosage:

Adults and children 12 years and older:

3 tablets per day, taking 1 tablet every 4 to 6 hours.

2.3 Acute Dosage: Adults and children 12 years and older:

1 tablet every ½ to 1 hour until symptoms lessen, then continue with standard dosage. Do not exceed 12 tablets in 24 hours.

3 Dosage Forms and Strength

300 mg tablets each containing the active ingredients in the strengths listed under Description. (11)

4 Contraindications

- WellMind™ Vertigo Tablets are contraindicated in patients with known hypersensitivity to WellMind™ Vertigo or any of its ingredients.
- Do not use during pregnancy or breastfeeding.

5 Warnings and Precautions

None

6 Adverse Reactions

6.1 Post-marketing Experience

- No adverse events with a causal relationship to WellMind™ Vertigo tablets have been reported.

7 Drug Interactions

No interactions have been reported, and none are expected due to the homeopathic dilutions.

8 Use in Specific Populations

8.1 Pregnancy

8.1.1 Teratogenic effects

Pregnancy Category C. Some ingredients in WellMind™ Vertigo Tablets have been shown to be teratogenic in various animal species when given in doses several thousand times the human dose. There are no adequate and well-controlled studies in pregnant women. WellMind™ Vertigo Tablets should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.1.2 Non-teratogenic effects

No known non-teratogenic effects.

8.2 Labor and Delivery

No recognized use in labor or delivery.

8.3 Nursing Mothers

Do not use during lactation.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established. However, traditional homeopathic use of the ingredients in WellMind™ Vertigo Tablets have not identified differences in responses between adults and pediatric patients.

8.5 Geriatric Use

Safety and effectiveness in geriatric patients have not been established. However, traditional homeopathic use of the ingredients in WellMind™ Vertigo Tablets have not identified differences in responses between adults and geriatric patients.

10 Overdosage

No negative effects of an overdose have been reported and none are expected due to the homeopathic dilutions.

11 Description

11.1 Ingredients

- Each 300 mg tablet contains:

Active Ingredients:			
Ingredient name	Potency	Quantity	Final dilution
Anacardium orientale	6X	10 mg	7.5X
Cocculus indicus	4X	210 mg	4.15X
Conium maculatum	3X	30 mg	4X
Petroleum	8X	20 mg	9.2X
Selenium metallicum	6X	10 mg	7.5X
Selenium metallicum	12X	10 mg	13.5X
Selenium metallicum	30X	10 mg	31.5X

Inactive Ingredients:

Lactose, Magnesium stearate

11.2 Pharmaceutical Form

- Tablets

11.3 Route of Administration

- Oral

12 Clinical Pharmacology

12.1 Mechanism of Action

The exact mechanism of WellMind™ Vertigo Tablets is not fully understood.

12.2 Pharmacodynamics

Not applicable for homeopathic medicinal products.

15 References

- Homeopathic Pharmacopeia of the United States Revision Service

16 How Supplied/Storage and Handling

16.1 Dosage forms and package sizes

- Bottle with 100 tablets
- NDC 50114-9001-2

16.2 Storage and handling

- Store at room temperature. Protect from light and moisture.
- Keep out of reach of children