DIZIBEAT

Betahistine 8 mg, 16 mg and 24 mg Tablets

La Renon

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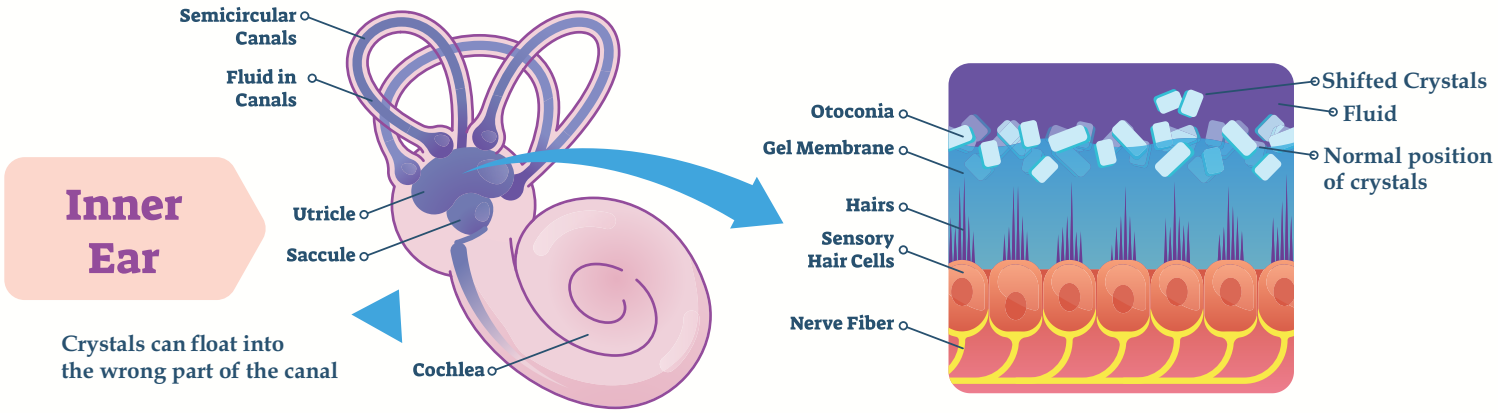
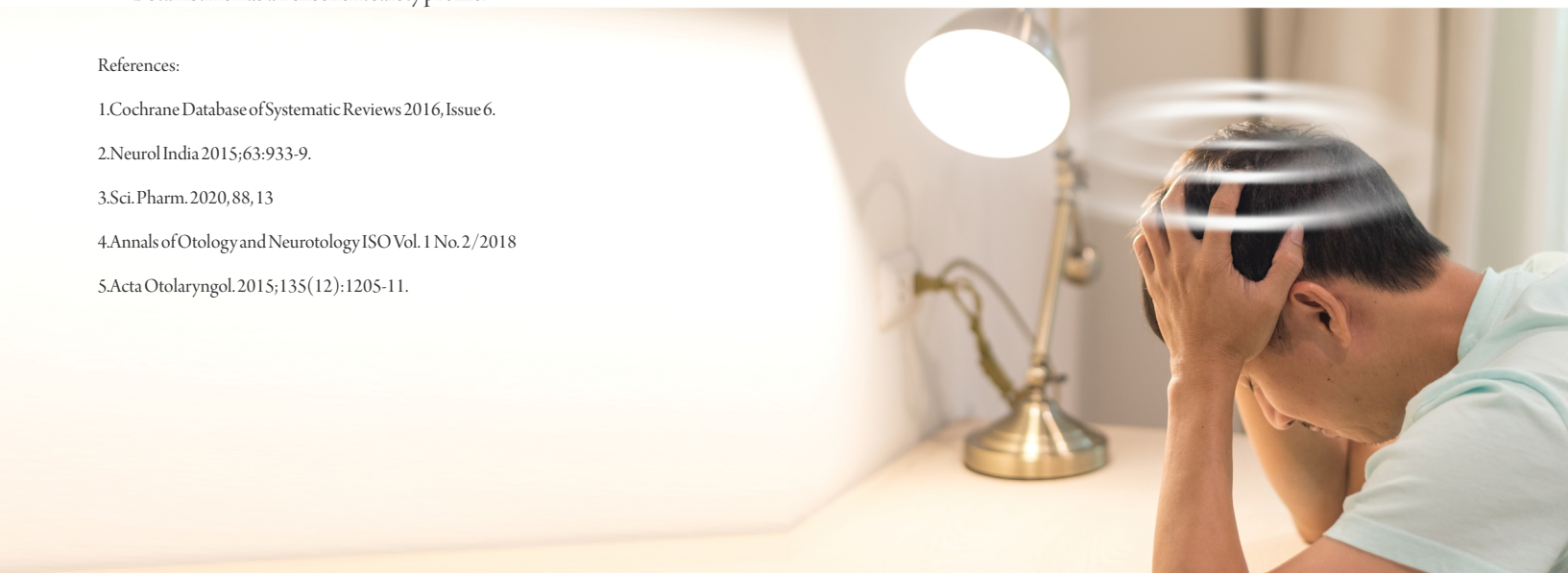
Background

- Vertigo is a symptom in which individuals experience a false sensation of movement.[1]
- This type of dizziness is thought to originate in the inner ear labyrinth or its neural connections.[1]
- Betahistine is a drug that works by improving blood flow to the inner ear.[1]
- After headache, vertigo is the second most common symptom encountered in patients in neurological outpatient facilities around the world.[2]



Salient feature of Betahistine

- Betahistine is generally well-tolerated as an anti-vertigo drug.[1]
- Orally administered betahistine hydrochloride demonstrates rapid and complete absorption from all parts of the gastrointestinal tract.[3]
- Compared with all other anti-vertigo drugs, betahistine has the least adverse effects and is a safe drug even at reasonably high doses.[4]
- Betahistine has an excellent safety profile.[5]



References:

1.Cochrane Database of Systematic Reviews 2016, Issue 6.

2.Neurol India 2015;63:933-9.

3.Sci. Pharm. 2020, 88, 13

4.Annals of Otology and Neurotology ISO Vol. 1 No. 2/2018

5.Acta Otolaryngol. 2015;135(12):1205-11.

Clinical Effectiveness

1)Assess the effectiveness and safety of oral betahistine in treatment naïve patients with acute peripheral vertigo, administered over 21 days.

Ref: Int J Otorhinolaryngol Head Neck Surg 2020; 6:1030-5.

Methods:

- Open-label, single-arm, interventional study based on clinical diagnosis with confirmed peripheral vertigo naive patients.
- Patients received 48 mg betahistine 16 mg, TDS (ter die sumendum - to be taken three times daily) for 21 days, and were followed up on day 1, 3, 7 and 21.

Results:

- No significant improvement in scale for vestibular vertigo severity level and clinical response evaluation (SVVSLCRE) score was noted from baseline to day 1, but significant reduction was seen from day 3 onwards and continued till day 21.
- A significant reduction in mean change of dizziness handicap inventory (DHI) scale was observed from baseline to day 3, day 7 and day 21.
- No major therapy related serious adverse events reported.

Conclusions:

- Findings suggest that 48 mg betahistine (16 mg, TID) therapy is effective in treatment naive patients with acute peripheral vertigo.
- Reduction in vertigo symptoms score is significant from day 3 to day 21.
- Betahistine is safe and easily tolerated by patients.

2) Betahistine is effective in improving vertigo-associated symptoms, with longer treatment periods leading to greater improvements.

Ref: The VIRTUOSO study. PLoS ONE 2017, 12(3): e0174114.

Methods

- Patients with vestibular vertigo were prescribed 48 mg/day betahistine, enrolled in Russia and Ukraine.
- Treatment duration was up to 2 months, and patients were followed up for 2 months after discontinuation of betahistine.

Results

- Overall, 309 patients were enrolled and 305 completed the study.
- Monthly vertigo attack frequency decreased significantly during the 2 months of treatment ($p < 0.001$ from baseline) and further decreased during the 2-month follow-up ($p < 0.001$ from end of treatment).
- Overall, clinical response graded good or excellent by 94.4% of physicians and 95.4% of patients.

Conclusion

- Finding suggest that betahistine (48 mg/day) therapy is effective in treating vertigo in routine clinical settings.

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Description

DIZIBEAT is an uncoated tablet containing Betahistine in the strength of 8 mg and 16 mg tablets. Betahistine is N-methyl-2- (2-pyridyl) ethylamine dihydro-chloride. Betahistine is a structural analogue of histamine.[1]

Mechanism of action

The primarily action of betahistine is to modulate the histaminergic system. It has a strong activity as an antagonist for histamine H3 receptors and a weak activity as an agonist for histamine H1 receptors, with virtually no activity on H2 receptors.

In the inner ear, betahistine has a potent antagonistic effect at H3 receptors, and increases the levels of neurotransmitters released from the nerve endings. The increased amounts of histamine released from histaminergic nerve endings stimulates H1 receptors, thus augmenting the direct agonistic effects of betahistine on these receptors. This explains the potent vasodilatory effects of betahistine in the inner ear and the efficacy of betahistine in the treatment of vertigo.[2]

Indication

Betahistine is indicated in vestibular disorders, Vertigo disease.

Dosage:

The recommended dosage for adults is 24–48 mg administered across several doses during the day.

Storage

Store protected from light and moisture, at a temperature not exceeding 30° C.

References:
1. Ann Otol Neurotol ISO 2018;1:51–57
2.Acta Otolaryngol. 2015;135(12):1205-11.

Hello

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