Abbreviated Prescribing Information:

Vertin*

GENERIC NAME: Betahistine Tablets IP 8/16/24 mg
BRAND NAME: VERTIN®, QUALITATIVE AND QUANTITATIVE COMPOSITION: Each uncoated tablet contains: Betahistine Hydrochloride IP 8mg/ 16mg/ 24mg and excipients qs. THERAPEUTIC INDICATIONS: Indicated for the symptomatic treatment of vertigo caused due to conditions including Meniere's syndrome. POSOLOGY AND METHOD OF ADMINISTRATION: The dosage for adults is 24-48 mg divided over the day. CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients. Phaeochromocytoma. SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Patients with bronchial asthma and history of peptic ulcer need to be monitored during therapy. May cause allergic reactions (possibly delayed). PREGNANCY AND LACTATION: There are no adequate data from the use of betahistine in pregnant women. It is not known whether betahistine is excreted in human milk. UNDESIRABLE EFFECTS: Undesirable effects reported during clinical trials (common >1/100, <1/10) with betahistine include nausea and dyspepsia and headache. Hypersensitivity reactions, e.g. anaphylaxis Mild gastric complaints (e.g. vomiting, gastrointestinal pain, abdominal distension and bloating). These can normally be dealt with by taking the dose during meals or by lowering the dose. Cutaneous and subcutaneous hypersensitivity reactions, in particular angioneurotic oedema, urticaria, rash, and pruritus. ISSUED ON: 13th Jun 2022. SOURCE: Prepared based on full prescribing information, version 6 dated 13th Jun 2022.
TM / * Trademark of the Abbott Group of Companies. For full prescribing information, please contact: Medical Sciences Division, Abbott India Limited, Godrej BKC, Plot No. C – 68, BKC, Near MCA Club, Bandra (E), Mumbai – 400 051.

Vertin* DT

GENERIC NAME: Betahistine hydrochloride orally disintegrating tablet, 8 mg/16 mg/24 mg.
BRAND NAME: VERTIN® DT, QUALITATIVE AND QUANTITATIVE COMPOSITION: Each orally disintegrating tablet contains: Betahistine hydrochloride I.P.... 8 mg/16 mg/24 mg. Excipients..... q.s. THERAPEUTIC INDICATIONS: Indicated for the symptomatic treatment of vertigo-causing conditions, including Ménière disease. POSOLOGY AND METHOD OF ADMINISTRATION: The dosage for adults is 24-48 mg divided over the day. The dosage should be individually adapted, according to the response. Improvement can sometimes only be observed after a couple of weeks of treatment. The best results are sometimes obtained after a few months. Pediatric population: Betahistine is not recommended for use in children below 18 years due to insufficient data on safety and efficacy. Geriatric population: Although there are limited data from clinical studies in this patient group, extensive post post-marketing experience with betahistine suggests that no dose adjustment is necessary in this patient population. Renal impairment: There are no specific clinical trials available in this patient group, but according to the post-marketing experience with betahistine no dose adjustment appears to be necessary. Hepatic impairment: There are no specific clinical trials available in this patient group, but according to post-marketing experience with betahistine no dose adjustment appears to be necessary. CONTRAINDICATIONS: Hypersensitivity to the active substance or any of the excipients. Pheochromocytoma. SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Patients with bronchial asthma and history of peptic ulcer need to be carefully monitored during therapy. May cause allergic reactions (possibly delayed). Betahistine orally disintegrating tablet contains aspartame - a source of phenylalanine. May be harmful for people with phenylketonuria. Betahistine orally disintegrating tablet contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency should not take this medicine. PREGNANCY AND LACTATION: There are no adequate data from the use of betahistine in pregnant women. The potential risk for humans is unknown. Betahistine should not be used during pregnancy unless clearly necessary. It is not known whether betahistine is excreted in human milk. There are no animal studies on the excretion of betahistine in milk. The importance of the drug to the mother should be weighed against the benefits of nursing and the potential risks for the child. UNDESIRABLE EFFECTS: In a bioequivalence study in healthy, adult, human subjects - Betahistine dihydrochloride orally disintegrating tablets (24 mg) were found to be safe and well-tolerated. Gastrointestinal disorders - Common: Nausea and dyspepsia; Nervous system disorders - Common: Headache; Immune system disorders- Hypersensitivity reactions, e.g., anaphylaxis; Gastrointestinal disorders - Mild gastric complaints; Skin and subcutaneous tissue disorders - Cutaneous and subcutaneous hypersensitivity reactions. ISSUED ON: 5th May 2021. SOURCE: Prepared based on full prescribing information, version 1.0, dated 5th May 2021.
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Vertin* OD

GENERIC NAME: Betahistine Hydrochloride Sustained Release Tablets 24/32/48 mg
BRAND NAME: Vertin® OD 24 mg/ 32 mg/ 48 mg. QUALITATIVE AND QUANTITATIVE COMPOSITION: Each Film Coated Sustained Release Tablet Contains: Betahistine Dihydrochloride I.P. 24 mg/32mg/48mg, Colour: Titanium Dioxide IP.THERAPEUTIC INDICATIONS: Treatment of Meniere's Syndrome, characterized by unilateral or bilateral tinnitus, vertigo, sensorineural hearing loss. For the symptomatic treatment of peripheral vertigo. POSOLOGY AND METHOD OF ADMINISTRATION: The dosage for adults is 24-48 mg per day. CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients. Phaeochromocytoma. SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Patients with bronchial asthma and history of peptic ulcer need to be carefully monitored during therapy. May cause allergic reactions (possibly delayed). PREGNANCY AND LACTATION: Betahistine should not be used during pregnancy unless clearly necessary. Lactation: It is not known whether betahistine is excreted in human milk. The importance of the drug to the mother should be weighed against the benefits of nursing and the potential risks for the child. UNDESIRABLE EFFECTS: Undesirable effects reported during clinical trials (common >1/100, <1/10) with betahistine include nausea and dyspepsia and headache. Hypersensitivity reactions, e.g. anaphylaxis Mild gastric complaints (e.g. vomiting, gastrointestinal pain, abdominal distension and bloating). These can normally be dealt with by taking the dose during meals or by lowering the dose. Cutaneous and subcutaneous hypersensitivity reactions, in particular angioneurotic oedema, urticaria, rash, and pruritus.
ISSUED ON: 19th July 2022 SOURCE: Prepared based on full prescribing information, version 6, dated 11th July 2022
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For full prescribing information, please contact: Medical Sciences Division, Abbott India Limited, Godrej BKC, Plot No. C – 68, BKC, Near MCA Club, Bandra (E), Mumbai – 400 051.

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

For full prescribing information, please contact: Abbott India Limited, Floor 16, Godrej BKC, Plot No. C – 68, BKC, Near MCA Club, Bandra (E), Mumbai – 400 051.
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