



Tinnitus

Hearing Loss

Vertigo



Meniere's disease

Vestibular compensation

Get your life balanced

Beta-synto

Betahistine

BETA-SYNTO 8mg • BETA-SYNTO 16mg • BETA-SYNTO 24mg



CODAL-SYNTO

Summary of the SPC for Beta-Synto

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| Name of the Medicinal Product: | Beta-Synto |
| Qualitative and Quantitative Composition: | Each tablet contains 8/16/ 24 mg betahistine dihydrochloride. |
| Pharmaceutical Form: | Tablet. |
| Therapeutic Indications: | Vertigo, tinnitus and hearing loss associated with Ménière's syndrome. |
| Posology and Method of Administration: | The usual daily dose is 24mg - 48mg betahistine dihydrochloride, divided into 2 or 3 equal doses. There are no dosage recommendations for children. |
| Contra-indications: | Hypersensitivity; Phaeochromocytoma. |
| Special Warnings and Precautions for Use: | Patients with a history of peptic ulcers; Patients with bronchial asthma. This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose – galactose malabsorption should not take this medicine. |
| Interactions with Other Medicinal Products and Other Forms of Interaction: | No in-vivo interaction studies have been performed. Based on in-vitro data no in-vivo inhibition on Cytochrome P450 enzymes is expected. Although an antagonism between betahistine and antihistamines could be expected on a theoretical basis, no such interactions have been reported. |
| Pregnancy and Lactation: | Betahistine should not be used during pregnancy unless clearly necessary. 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: | Nausea, dyspepsia; Hypersensitivity reactions; Headache; Mild gastric complaints; Cutaneous and subcutaneous hypersensitivity reactions, angioneurotic oedema, urticaria, rash, pruritus. |
| Date of revision of the text: | 02/2014. |

MAH: Codal Synto Ltd.

