1. NAME OF THE MEDICINAL PRODUCT

STUNARONE TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

A STUNARONE tablet contains 25 mg cinnarizine.
Excipients with known effect: each tablet contains 158.8 mg lactose monohydrate and 15 mg sucrose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White, circular, biconvex, half scored tablet with the inscription “JANSSEN” on one side and “S/25” on the other side.

4. CLINICAL PARTICULARS

4.1Therapeutic indications

Symptomatic treatment of nausea and vertigo due to Meniere's disease and other labyrinthine disturbances and for travel sickness.

4.2 Posology and method of administration

Posology
Disorders of balance:
In adults: 1 tablet of 25 mg t.i.d.

Motion sickness:
in adults: 1 tablet of 25 mg half an hour before traveling; to be repeated every 6 hours.
in children (5-12): half of the adult dose is recommended.

Method of administration
STUNARONE should preferably be taken after meals with some liquid.
STUNARONE may be divided at the score line only for easier administration, but not for administering a partial dose. Please use a tablet divider to achieve half a dosage.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients mentioned in section 6.1.

4.4 Special warnings and precautions for use

As with other antihistamines, Stunarone may cause epigastric problems, taking it after meals may diminish gastric irritation.

In patients with Parkinson's disease, STUNARONE should only be given if the advantages outweigh the possible risk of aggravating this disease.

Stunarone may cause somnolence, especially at the start of treatment. Therefore, caution should be taken when alcohol, central nervous system (CNS) depressants or tricyclic antidepressant medicines are used concomitantly

In patients with porphyria, the safety of cinnarizine is not established. Consult a porphyria specialist for additional advice.

STUNARONE tablets contain lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption, should not take this medicine.

STUNARONE tablets also contain sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Interference with diagnosis:
Due to the anti-histamine effect, STUNARONE may prevent the normal positive response to dermal reactivity indicators if used up to 4 days prior to the skin tests.

4.5 Interaction with other medicinal products and other forms of interaction

Alcohol, CNS depressants and tricyclic antidepressants:
The sedative effects of STUNARONE and of any of the following substances may be potentiated when used concomitantly: alcohol, CNS depressants or tricyclic antidepressants.

4.6 Pregnancy and lactation

Pregnancy
Although in animal studies, STUNARONE has shown no teratogenic effects, as with all drugs, STUNARONE should be used during pregnancy only if the therapeutic benefits outweigh the potential risks for the fetus.

Breastfeeding:
There are no data on the excretion of STUNARONE in human breast milk:. nursing should therefore be discouraged in women using STUNARONE.

Fertility:
The effect of cinnarizine on human fertility has not been investigated.

4.7 Effects on ability to drive and use machines

Since, especially at the start of treatment, somnolence may occur, caution should be taken during activities such as driving or operating machinery.

4.8 Undesirable effects

The safety of STUNARONE tablets was evaluated in 303 cinnarizine-treated subjects who participated in 6 placebo-controlled trials for the indications peripheral circulatory disorders, cerebral circulatory disorders, vertigo and the prevention of motion sickness; and in 937 cinnarizine-treated subjects who participated in 6 reference and 13 open label clinical trials for the indications peripheral circulatory disorders, cerebral circulatory disorders and vertigo. Based on pooled safety data from these clinical trials, the most commonly reported (>1% incidence) Adverse Drug Reactions (ADRs) were: somnolence (9.9%), nausea (3.0%) and weight increased (1.5%).

Including the above mentioned ADRs, the following ADRs have been observed from clinical trials and post-marketing experiences reported with the use of STUNARONE . Frequencies displayed use the following convention:

Very common: (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); Not known (cannot be estimated from the available data).

Nervous system disorders

Common: Sleepiness .
Uncommon: Hypersomnia.
Not known: Dyskinesia, extrapyramidal disorders, parkinsonism, tremor.

Gastrointestinal disorders
Common: Nausea.
Uncommon: Vomiting.
Rare: pain in upper abdominal, dyspepsia.

Hepatobiliary disorders
Not known: Jaundice cholestatic.

Skin and subcutaneous tissue disorders
Uncommon: Hyperhidrosis. Lichenoid keratosis
Not known: Lichen planus, subacute cutaneous lupus erythematosus.

Musculoskeletal and connective tissue and bone disorders

Not known*:* Muscle rigidity.

General disorders and administration site conditions

Uncommon*:* Fatigue

Investigations

Common*:* Weight increased.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il/

4.9 Overdose

Symptoms and signs

Acute cinnarizine overdoses have been reported with doses ranging from 90 to 2,250 mg. The most commonly reported signs and symptoms associated with an overdose of cinnarizine include: alterations in consciousness ranging from somnolence to stupor and coma, vomiting, extrapyramidal symptoms and hypotonia. In a small number of young children, seizures developed. Clinical consequences were not severe in most cases, but cases of death have been reported after single and polymedication overdoses involving cinnarizine.

Treatment

There is no specific antidote. For any overdose, a symptomatic and supportive treatment is recommended. It is advisable to contact a poison control center to obtain the latest recommendations for the management of an overdose.

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antivertigo substances, ATC code N07CA02

Mechanism of action

Cinnarizine inhibits contractions of vascular smooth muscle cells by blocking calcium channels. In addition to this direct calcium antagonism, cinnarizine decreases the contractile activity of vasoactive substances, such as noradrenaline and serotonin, by blocking receptor-dependent calcium channels. Blockade of the cellular calcium influx is tissue-selective and results in anti-vasoconstrictor properties without effect on blood pressure and heart rate,
Cinnarizine may further improve deficient microcirculation by increasing erythrocyte deformability and decreasing blood viscosity. Cellular resistance to hypoxia is increased.
Cinnarizine inhibits stimulation of the vestibular system, which results in suppression of nystagmus and other autonomic disorders. Acute episodes of vertigo can be prevented or reduced by cinnarizine.

5.2 Pharmacokinetics properties

Absorption

The peak plasma concentrations of cinnarizine are obtained 1 to 3 hours after intake.

Distribution
Cinnarizine is bound for 91% to plasma proteins.

Biotransformation

Cinnarizine is extensively metabolised mainly via CYP2D6.

Elimination

The reported elimination half-life for cinnarizine varies from 4 to 24 hours. The elimination of metabolites occurs for about 1/3 in the urine and2/3 in the faeces.

5.3 Preclinical safety data

A comprehensive battery of nonclinical safety studies showed that effects were observed only after chronic exposures sufficiently above of the maximum human exposure, indicating little relevance to clinical use. No effects were shown in animal fertility evaluations, and no teratogenicity was shown in any study.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:
lactose monohydrate, maize starch, sucrose, talc, cottonseed oil hydrogenated, polyvidone K 90.

6.2 Incompatibilities

Not applicable

6.3 Shelf life
The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage
Store below 25° C.

6.5 Nature and contents of container

Blister containing 25 tablets

6.6 Special precautions for disposal and other instructions

Any unused medicinal product or waste material should be disposed of in accordance with the local requirements.

6 MARKETING AUTHORISATION HOLDER

Manufacturer: Janssen Cilag S.p.A., Via C. Janssen 04100, Borgo S.michele, Latina**Registration Holder:** J-C Health Care Ltd, Kibbutz Shefayim, 6099000, Israel

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