PROFESSIONAL INFORMATION

SCHEDULING STATUS

Schedule 2

1 NAME OF THE MEDICINE

STUGERON® tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cinnarizine 25 mg per tablet

Contains sugar (lactose monohydrate and sucrose)

Each tablet contains 158,8 mg lactose monohydrate and 15 mg sucrose.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

A white, circular, slightly arched, biconvex half-scored tablet, embossed with “S/25” on one side and “JANSSEN" on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Disorders of balance – maintenance therapy for symptoms of labyrinthine disorders, including vertigo, dizziness, tinnitus, nystagmus, nausea and vomiting.

Prophylaxis of motion sickness.

4.2 Posology and method of administration

Posology

STUGERON should preferably be taken after meals

Disorders of balance-Adults*:* 1 x 25 mg tablet three times daily.

The maximum recommended dosage should not exceed 225 mg (9 tablets) daily - if necessary the dosage may be divided over 2 or 3 intakes per day. As the effect of STUGERON tablets on vertigo is dose dependent, the dosage should be increased progressively.

Prophylaxis of Motion sickness

Adults: 25 mg may be taken at 2 hours before the start of the journey and 12,5 mg (half a tablet) to 25 mg may be repeated every 8 hours during the journey when necessary.

Children 8 to 12 years: 12,5 mg (half a tablet) three times daily when necessary.

4.3 Contraindications

Hypersensitivity to cinnarizine or any of the excipients listed under the heading COMPOSITION.

Parkinson's disease.

4.4 Special warnings and precautions for use

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

STUGERON may cause epigastric distress, taking it after meals may diminish gastric irritation.

Lactose warning

STUGERON tablets contain lactose. Patients with the rare hereditary conditions of galactose intolerance, e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take STUGERON.

Sucrose warning

STUGERON tablets contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take STUGERON.

Lactose and sucrose may have an effect on the glycaemic control of patients with diabetes mellitus.

4.5 Interaction with other medicines and other forms of interaction

Alcohol, CNS depressants and tricyclic antidepressants

STUGERON may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, tricyclic antidepressants, sedatives and tranquillisers.

The side-effects of anticholinergic substances such as atropine and tricyclic antidepressants may be enhanced by the concomitant administration of STUGERON.

Monamine-oxidase inhibitors may enhance the antimuscarinic effects of STUGERON.

Diagnostic interference

STUGERON tablets may prevent otherwise positive reactions to dermal reactivity indicators if used up to 4 days prior to skin testing.

4.6 Fertility, pregnancy and lactation

The safety of STUGERON tablets in pregnant and lactating women has not been established.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Clinical Trial Data

Side-effects reported by ≥ 1 % of STUGERON-treated subjects

System/Organ Class	%
Nervous System Disorders Somnolence	8,3
Gastrointestinal Disorders Nausea	1,5
Investigations Weight increased	2,1

Side-effects reported by < 1% of STUGERON-treated subjects

Nervous System Disorders
Hypersomnia
Lethargy
Gastrointestinal Disorders
Vomiting
Abdominal Pain upper
Dyspepsia
Skin and Subcutaneous Tissue Disorder
Hyperhidrosis
General Disorders and administration Site Conditions
Fatigue

Postmarketing data

Side-effects identified during postmarketing experience and based on spontaneous reporting rates

System/Organ Class
Nervous System Disorders
Dyskinesia
Extrapyramidal disorder
Parkinsonism
Tremor
Hepatobiliary Disorders
Jaundice cholestatic
Skin and Subcutaneous Tissue Disorder

Lichenoid keratosis Lichen planus Subacute cutaneous lupus erythematosus
Musculoskeletal Connective Tissue and Bone Disorders Muscle rigidity

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 medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the :**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Symptoms

The signs and symptoms are mainly due to the anti-cholinergic (atropine- like) activity of Cinnarizine.

Acute STUGERON overdoses have been reported with doses ranging from 90 to 2 250 mg. The most commonly reported signs and symptoms include: alterations in consciousness ranging from somnolence to stupor and coma, vomiting, extrapyramidal symptoms and hypotonia. Hypertension and convulsions may also occur in adults. Overdose may be fatal especially in infants and children in whom the main symptoms are central nervous system stimulation and antimuscarinic effects including ataxia, excitement, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia. Deepening coma, cardiorespiratory collapse, and death may occur within

18 hours. In adults, the usual symptoms are central nervous depression with drowsiness, coma and convulsions.

Treatment

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification

A 5.7. Antihistaminics, anti-emetics and antivertigo preparations

Mechanism of action

Cinnarizine inhibits contractions of vascular smooth muscle cells by blocking calcium channels. Cinnarizine increases erythrocyte deformability and decreases blood viscosity *in vitro.* Cinnarizine inhibits stimulation of the vestibular system.

5.2 Pharmacokinetic properties

Absorption

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

Distribution

The plasma protein binding of cinnarizine is 91 %

Metabolism

Cinnarizine is completely metabolized

Excretion

Cinnarizine disappears from plasma with a half-life of 4 hours.

About 1/3 of these metabolites are eliminated in the urine and 2/3 in the faeces.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cotton seed oil hydrogenated

lactose monohydrate,

maize starch,

polyvidone,

sucrose

talc.

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

3 years

6.4 Special precautions for storage

Store at or below 30° C in a dry place. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of the container

Cartons containing one or more blister packs of 10, 20 or 25 tablets each

7 HOLDER OF CERTIFICATE OF REGISTRATION



JANSSEN PHARMACEUTICA (PTY) LTD

(Reg. No. 1980/011122/07)

2 Medical Road, Halfway House, Midrand, 1685

Tel: + 27 (0)11 518 7000

RA-JACZA-MedInfo@its.jnj.com

8 REGISTRATION NUMBER

C/5.7/590

9 DATE OF FIRST AUTHORISATION

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10 DATE OF REVISION OF THE TEXT:

14 June 2022