Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Stugeron 25 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 25mg cinnarizine.
Excipients: Contains lactose monohydrate 158.8mg and sucrose 15.0mg
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
White tablets marked 'JANSSEN' on one side and 'S/25' on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Stugeron is indicated in peripheral vascular disease when such symptoms as intermittent claudication and cold extremities exist and in vasospastic disorders.

4.2 Posology and method of administration

Stugeron Tablets are for oral administration to adults.

Peripheral Vascular Disease:

The usual dose is 50 to 75 mg (2-3 tablets) two to three times daily.

Stugeron should preferably be taken after meals. These doses should not be exceeded.

Peripheral arterial disease is slow to improve with any form of drug treatment. Maximum benefits with Stugeron will not be seen until after several weeks of continuous treatment although significant improvement in blood flow has frequently been demonstrated after 1 week.

Use in elderly: as above

Use in children: not recommended

4.3 Contraindications

Stugeron Tablets are contra-indicated in patients with known hypersensitivity to cinnarizine or to any excipients listed in Section 6.1.

4.4 Special warnings and precautions for use

As with other antihistamines, Stugeron may cause epigastric discomfort; taking it after meals may diminish gastric irritation.

Stugeron has not been found to reduce blood pressure significantly. However, the drug should be used with reasonable caution in hypotensive patients.

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

Stugeron may cause somnolence, especially at the start of treatment. Therefore, caution should be taken when alcohol or CNS depressants or tricyclic antidepressants are used concomitantly. (See section 4.5).

Diagnostic Interference:
Because of its antihistamine effect, Stugeron may prevent an otherwise positive reaction to dermal reactivity indicators if used within 4 days prior to testing.

Use of cinnarizine should be avoided in porphyria.

There have been no specific studies in hepatic or renal dysfunction. Stugeron should be used with care in patients with hepatic or renal insufficiency.

Patients with rare hereditary problems of fructose or galactose intolerance, LAPP lactase deficiency, glucose-galactose malabsorption or sucrase-isomaltase insufficiency, should not take this medicine because it contains lactose and sucrose.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use of alcohol, CNS depressants or tricyclic antidepressants may potentiate the sedative effects of either these drugs or of Stugeron.

Diagnostic Interference:
Because of its antihistamine effect, Stugeron may prevent an otherwise positive reaction to dermal reactivity indicators if used within 4 days prior to testing.

4.6 Fertility, pregnancy and lactation

Use in Pregnancy: The safety of Stugeron in human pregnancy has not been established although studies in animals have not demonstrated teratogenic effects. As with other drugs, it is not advisable to administer Stugeron in pregnancy.

Use in lactation: There are no data on the excretion of Stugeron in human breast milk; use of Stugeron is not recommended in nursing mothers.

4.7 Effects on ability to drive and use machines

Stugeron may cause drowsiness, especially at the start of treatment; patients affected in this way should not drive or operate machinery.

4.8 Undesirable effects

The safety of Stugeron was evaluated in 372 cinnarizine-treated subjects who participated in 7 placebo-controlled trials for the indications peripheral circulatory disorders, cerebral circulatory disorders, vertigo and seasickness; and in 668 cinnarizine-treated subjects who participated in six comparator and thirteen 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 (>2% incidence) Adverse Drug Reactions (ADRs) were: Somnolence (8.3) and Weight increased (2.1).
Including the above mentioned ADRs, the following ADRs have been observed from clinical trials and post-marketing experiences reported with the use of Stugeron.

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).

System Organ Class	Adverse Drug Reactions		
	Frequency Category		
	Common (≥ 1/100 to < 1/10)	**Uncommon** (≥ 1/1000 to < 1/100)	**Not Known**
Nervous System Disorders	Somnolence	Hypersomnia; Lethargy	Dyskinesia; Extrapyramidal disorder; Parkinsonism; Tremor
Gastrointestinal Disorders	Nausea	Stomach discomfort; Vomiting; Abdominal pain upper; Dyspepsia	
Hepatobiliary disorders			Cholestatic jaundice
Skin and Subcutaneous Tissue Disorders		Hyperhydrosis; Lichenoid keratosis	Lichens planus; Subacute cutaneous lupus erythematosus
Musculoskeletal and connective Tissue Disorders			Muscle rigidity
General Disorders and Administration Site Conditions		Fatigue	
Investigations	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. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms
Acute cinnarizine overdoses have been reported with doses ranging from 90 to 2,250 mg. The most commonly reported signs and symptoms associated with 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 deaths have been reported after single and polydrug overdoses involving cinnarizine.

Treatment
There is no specific antidote. For any overdose, the treatment is symptomatic and supportive care.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code N07CA02
Pharmacotherapeutic group: Antivertigo preparations

Cinnarizine's action in the treatment of peripheral vascular disease is due to its anti-vasoconstrictor properties, its action on blood hyperviscosity and its anti-ischaemic effect. Anti-vasoconstriction is thought to be through a calcium blocker mechanism and is evident selectively in vascular smooth muscle. Increased peripheral muscle blood flow may be mediated by prevention of calcium entry into ischaemic erythrocytes, thereby preserving flexibility.

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 extensively metabolised mainly via CYP2D6 in the liver.

Distribution
The reported elimination half-life for cinnarizine ranges from 4 to 24 hours. The elimination of metabolites occurs as follows: about one third in the urine and two thirds in the faeces. Plasma elimination half life is 3 to 4 hours.

5.3 Preclinical safety data

Nonclinical safety studies showed that effects were observed only after chronic exposures from approximately 5 to 72 times, on a mg/kg basis when compared to the maximum recommended human dose of 225 mg/day, calculated as 4.5 mg/kg as based on a 50 kg person.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Maize Starch
Sucrose
Talc
Povidone K90
Cotton Seed Oil - hydrogenated

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Blister packs of aluminium foil/PVC containing 50 tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Johnson & Johnson (Ireland) Limited
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0330/044/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1979

Date of last renewal: 15 October 2010

10 DATE OF REVISION OF THE TEXT

August 2018