PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

STUGERON®

25 mg Cinnarizine per tablet

Read all of this leaflet carefully because it contains important information for you

STUGERON is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use STUGERON carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share STUGERON with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

1. WHAT STUGERON CONTAINS

The active substance is cinnarizine. Each tablet contains 25 mg of cinnarizine.

The tablet also contains: cotton seed oil hydrogenated, lactose monohydrate, maize starch, polyvidone, sucrose, talc.

Contains sugar (lactose monohydrate and sucrose)

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

2. WHAT STUGERON IS USED FOR

STUGERON is used to treat the following:

- **Balance disorder** - STUGERON relieves the dizziness and spinning sensation ("vertigo") caused by problems of the inner ear. It also relieves the associated symptoms like persistent ringing in the ears ("tinnitus"), rapid and uncontrollable movements of the eyes, nausea and vomiting;
- **Circulatory disorders of the brain** – STUGERON relieves symptoms caused by a disturbed blood circulation of the brain, such as dizziness, and spinning sensation ("vertigo"), persistent ringing in the ears ("tinnitus'), concentration and memory disturbances, irritability and certain kinds of headache;
- **Circulatory disorders of the limbs** – STUGERON relieves symptoms caused by disturbed blood circulation of the arms and legs, such as pain in the legs while walking, leg ulcers, cold or numb fingers and toes, and cramps in the calves at night;
- STUGERON also prevents motion sickness.

3. BEFORE YOU TAKE STUGERON

Always inform your doctor or pharmacist if you are using other medicines because some medicines should not be taken together.

Do not take STUGERON if:

- you are hypersensitive (allergic) to cinnarizine or any of the ingredients of STUGERON
- you suffer from Parkinson's disease.

Take special care with STUGERON:

Other medicines and alcohol:

Medicines for depression and medicines that slow up your reactions (sleeping pills, tranquilisers and strong pain killers) can have an increased calming effect when taken with STUGERON.

Tell your doctor if you are taking any other medicines.

Alcohol and STUGERON strengthen each other's dulling effect. You should therefore limit the amount of alcohol you drink while on STUGERON.

Taking STUGERON with food and drink:

You should take STUGERON after meals. The tablets are best taken with a little water.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or healthcare professional for advice before taking STUGERON.

Driving and using machinery:

STUGERON may lead to drowsiness and impaired concentration. Especially at the start of treatment STUGERON can cause drowsiness, which can make you less alert and reduce your driving ability. So, you should be careful about using machines or driving while on STUGERON.

Important information about some ingredients of STUGERON:

STUGERON contains "lactose" (a type of sugar). Patients with rare hereditary conditions of lactose/fructose or galactose intolerance should not take STUGERON.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking STUGERON.

STUGERON contains sugars (lactose and sucrose), which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with STUGERON:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Some of the interactions are listed below:

- Medicines for depression, sleeping pills, tranquillisers and strong painkillers can have an increased effect when taken with STUGERON.
- Alcohol and STUGERON strengthen each other's sedative effect. You should not drink while on STUGERON.

4. HOW TO TAKE STUGERON

Do not share medicines prescribed for you with any other person. Always take STUGERON as your doctor has instructed you. You should check with your doctor of pharmacist if you are unsure.

Your doctor will tell you how much STUGERON you should take. It is best to start with a small amount of STUGERON, after which the dose can gradually be increased until the desired result is obtained. Your doctor will explain exactly how you should proceed.

In most cases one of the following doses is prescribed:

Adults and children over the age of 12 years:

For a disturbed blood circulation of the arms or legs, and in particular for pain in the legs while walking (*Peripheral circulatory disorders):* 2 to 3 x 25 mg tablets three times daily.

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

Motion sickness:

Adults: 25 mg may be taken 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.

This formulation is not suitable for children less than 8 years old.

You should take STUGERON a half hour before you leave for a trip, and for long trips you can take it every 6 hours after that.

Important!

The maximum recommended dosage should not exceed 225 mg (9 tablets) daily in adults- 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.

If you take more STUGERON than you should:

Taking too much STUGERON, can lead to the following signs and symptoms: alterations in consciousness ranging from sleepiness to loss of consciousness, vomiting, muscle weakness or incoordination, and convulsions. Death was reported in association with cinnarizine overdose.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

5. POSSIBLE SIDE EFFECTS

STUGERON can have side effects. Not all side effects reported for STUGERON are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking STUGERON, please consult your doctor, pharmacist or other healthcare professional for advice.

Listed below are side-effects (also called adverse drug reactions) related to treatment with STUGERON.

Frequent

- Sleepiness
- Discomfort in the stomach
- Weight gain

Less frequent

- Prolonged nocturnal sleep
- Vomiting, discomfort after meals, stomach ache
- Excessive sweating
- Tiredness
- Liver problem that causes yellowing of the skin or eyes (jaundice)
- Itchy red lesions or rash on the skin or grey white pimples in the mouth
- Movement problems like jerky movements, muscle stiffness, trembling. These symptoms are also known as “extrapyramidal symptoms” (EPS)
- Red circular lesions or rash that occur on sun exposed skin areas.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF STUGERON

Store at or below 25°C (at normal room temperature). Protect from light.

Keep all medicines in their original packaging and in a dry pace (never in the bathroom, for example).

STUGERON can be kept for only a limited period. Do not use STUGERON after the date (month and year) printed after "EXP", even if it has been stored properly.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (i.e. toilets).

7. PRESENTATION OF STUGERON

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

8. IDENTIFICATION OF STUGERON

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

9. REGISTRATION NUMBER/REFERENCE NUMBER

C/5.7/590

Nam. Reg. No.: 04/5.7/0259 NS 1 Botswana Reg. No.: B93155102

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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