

Package leaflet: information for the user

Stugeron 25 mg tablets

Cinnarizine

Please read this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This also applies to any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 to 14 days.

What is in this leaflet?

1. What Stugeron is and what it is used for
2. What you need to know before you take Stugeron
3. How to use Stugeron
4. Possible side effects
5. How to store Stugeron
6. Contents of the pack and other information

1. What Stugeron is and what it is used for

Stugeron is used to provide adults with relief from:

- light headedness and vertigo cause by inner ear problems. Stugeron also relieves the associated symptoms such as persistent tinnitus (ringing of the ears), rapid, involuntary eye movements, nausea and vomiting;
- symptoms caused by problems with brain blood circulation, such as lightheadedness, persistent tinnitus (ringing of the ears), difficulty concentrating and remembering things, anti-social behavior, irritability and certain types of headaches;
- symptoms caused by blood circulation problems in the arms and legs, such as pain in the legs when walking, leg ulcers, hands and/or feet turning blue, cold sensation or lack of sensitivity in the fingers and toes and nocturnal cramps of the calf.

Stugeron also prevents travel sickness and migraine in adults.

Stugeron is used to prevent travel sickness in children aged 6 years old and over.

2. What you need to know before you use Stugeron

Do not use Stugeron:

- if you are allergic to the active substance or any of the other ingredients in this medicine (listed in section 6).

Warnings and precautions

- if you have Parkinson's disease. Tell your doctor, who will determine whether or not you can take Stugeron.

- if you are taking other medicines. In this case, see also "Other medicines and Stugeron".

- if you have problems in terms of the formation of hemoglobin (porphyria). Your doctor will consult a specialist for additional advice.

Other medicines and Stugeron

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including those available over the counter.

Taking Stugeron may increase the calming effect of anti-depressants and medicines that slow down your reactions (sleeping tablets, tranquilizers and strong painkillers).

Stugeron with food, drink and alcohol

Using alcohol and Stugeron together increases their sedative effects. You must therefore limit your alcohol consumption when you are taking Stugeron.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. He will decide whether or not you can use Stugeron.

It is recommended that you do not breastfeed if you are taking Stugeron, as small amounts of the medicine could be excreted into the breast milk.

There are no human data on the effect of Stugeron on fertility.

Driving and using machines

Stugeron can cause drowsiness, particularly at the start of treatment, which can reduce your level of alertness and your capacity to drive a vehicle. You must be prudent when driving vehicles or using machinery when using Stugeron.

Stugeron tablets contain lactose monohydrate and sucrose.

If your doctor has told you that you have an intolerance to certain sugars, contact him or her before taking this medicine.

3. How to use Stugeron

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if in doubt.

Stugeron is available as tablets. Take this medicine after meals. The tablets should preferably be taken with a small amount of water..

Your doctor will tell you how much Stugeron to take.

Use in adults

25 mg tablets:

- The recommended dose for **balance disorders, brain blood circulation disorders and migraine prevention** is:

1 tablet, three times a day

- The recommended dose for **blood circulation disorders in the arms or legs** is:

2 to 3 tablets, three times a day

Important!

Do not take more than 9 tablets a day.

- The recommended dose for **travel sickness** is: 1 tablet.

You should take Stugeron at least half an hour before departure; in the event of a long journey, repeat the uptake every six hours.

Use in children and adolescents up to 18 years old

The recommended dose for **travel sickness** is:

- *Adolescents aged 13 years and older:* 1 tablet (the same dosage as in adults)
- *Children from 6 to 12 years inclusive:* 1/2 tablet

Take Stugeron at least half an hour before departure; in the event of a long journey, repeat the uptake every six hours.

If you take more Stugeron than you should

If you have used or taken too much Stugeron, immediately contact your doctor, pharmacist

Taking too much Stugeron can cause the following signs and symptoms: changes in consciousness ranging from drowsiness to loss of consciousness, vomiting, muscle weakness or poor coordination and convulsions. Some fatalities have been reported in connection with overdosage of cinnarizine. If you suspect an overdosage of Stugeron, contact your doctor.

If you forget to use Stugeron

Do not take a double dose to make up for the dose that you missed.

If you have further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Known side effects of Stugeron are below.

Common (occurring in at least 1 in 100 patients, but in fewer than 1 in 10 patients):

- Drowsiness
- Nausea
- Weight gain

Uncommon (occurring in at least 1 in 1,000 patients, but in fewer than 1 in 100 patients):

- Lengthening of nocturnal sleep time
- Vomiting, sensation of difficulty after meals, stomach pain, digestion problems
- Excessive Sweating
- Fatigue
- Red lesions accompanied by skin itching, skin rash or gray-white pustules in the mouth

Frequency unknown:

- Difficulty moving, such as jerky movements, muscular stiffness, tremors. These symptoms are also called “extrapyramidal symptoms” (EPS).
- Round, red lesions or skin rash if skin is exposed to the sun.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This also applies to any possible side effects not listed in this leaflet.

By reporting side effects, you will be helping to provide more information on the safety of this medicine.

5. How to store Stugeron

Store between 15°C and 30°C .

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging after “EXP”. The figures refer to a month and a year. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist to dispose of any medications you are no longer using. These measures will help to protect the environment.

6. Contents of the pack and other information

What Stugeron contains

Stugeron tablets

- The active substance is cinnarizine. Each tablet contains 25 mg cinnarizine.
- The other substances are: lactose monohydrate, maize starch, sucrose, talcum, Cottonseed oil hydrogenated, polyvidone K90, ..

What Stugeron looks like and contents of the pack

Tablets: round, white, biconvex tablet with a score line bearing the wording “JANSSEN” on one side and “S/25” on the other. blister of 50 or 200 tablets.

Not all pack sizes may be marketed.

Manufacturer:

See outer carton

This leaflet was last revised in: 30 January 2017

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children

Council of Arab Health Ministers, Union of Arab Pharmacists