

STUGERON® TABLET

Cinnarizine (25mg)

What is in this leaflet

1. What Stugeron® is used for
2. How Stugeron® works
3. Before you use Stugeron®
4. How to use Stugeron®
5. While you are using it
6. Side effects
7. Storage and Disposal of Stugeron®
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Stugeron® is used for

Stugeron is used to treat the following:

- **balance disorders** –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 loss, irritability, and certain kinds of headache; –Stugeron prevents migraine.
- **circulatory disorders of the limbs** – Stugeron relieves symptoms caused by disturbed blood circulation of the arms and legs, such as crampy pain in the legs while walking, leg ulcers, cold or numb fingers and toes, and cramps at night.

Stugeron also **prevents motion sickness.**

How Stugeron® works

The medicine in Stugeron is cinnarizine that helps symptoms

caused by balance or movement problems.

Before you use Stugeron®

-When you must not use it

Do not take Stugeron tablets if:

- You are allergic to cinnarizine or any of the other ingredients in Stugeron tablets (listed in "Product Description – Ingredients")
- Your child is under 5 years old

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Stugeron tablets.

-Pregnancy and Breastfeeding

If you are pregnant or plan to be pregnant, inform your doctor, who will decide if you can take Stugeron.

Stugeron should be used during pregnancy only if the therapeutic benefits justify the potential risks for the fetus.

If you are taking Stugeron, you are advised not to breast-feed since there are no data on the excretion of Stugeron in human breast milk.

-Before you start to use it

Parkinson's disease

If you have Parkinson's disease, tell your doctor, who will decide if you can take Stugeron.

-Taking other medicines

Medicines for depression and medicines that slow down your brain activity 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 effect. You should therefore limit the amount of alcohol you drink while on Stugeron.

How to use Stugeron®

Stugeron comes as tablets. You should take the medicine after meals. The tablets are best taken with a little water.

Your doctor will tell you how much Stugeron you should take.

-How much to use

For balance disorders, circulatory disorders of the brain:

The recommended dose is:

1 tablet three times a day

For circulatory disorders of the limbs:

The recommended dose is:

2 to 3 tablets three times a day

Important!

Do not take more than 9 tablets a day.

For motion sickness:

The recommended dose is:

Adults and adolescents aged 13 years and above:

1 tablet

Children aged 6 to 12 years:

1/2 tablet

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

-When to use it

Always take Stugeron exactly as your doctor has told you. You should check with your doctor if you are not sure.

-How long to use it

Continue taking Stugeron for as long as your doctor recommends.

-If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the

STUGERON® TABLET

Cinnarizine (25mg)

medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

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. If an overdose of Stugeron is suspected, you should call your doctor.

While you are using it

-Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Stugeron.

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

Do not take any new medicines without consulting your doctor.

Do not give Stugeron to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Driving and using machines

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.

Side effects

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

Common (reported by at least 1 in 100 patients but by fewer than 1 in 10 patients):

- Sleepiness
- Weight gain

Uncommon (reported by at least 1 in 1000 patients but by fewer than 1 in 100 patients):

- Prolonged daytime sleep
- Vomiting, stomach discomfort, upper abdominal pain
- Excessive sweating
- Tiredness
- Itchy red lesions or rash on the skin or white pimples in the mouth

Very rare (reported by fewer than 1 in 10,000 patients):

- 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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of Stugeron®

-Storage

This medicine 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 between 15 - 30°C
Store in a dry place

You are advised to return expired medicine to your pharmacist.

Keep out of the sight and reach of children.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

Stugeron 25 mg tablets are white and round with a score line, and with 'JANSSEN' printed on one side and 'S/25' on the other.

-Ingredients

Active ingredients

One tablet contains 25 milligrams of cinnarizine.

Inactive ingredients

The tablets also contain cotton seed oil hydrogenated, lactose monohydrate, maize starch, polyvidone, sucrose, talc and purified water.

-MAL number

MAL19871481A

Manufacturer

Janssen Cilag S.p.A.
Via C.Janssen
Borgo San Michele
Latina, Italy

Product Registration Holder

Johnson & Johnson Sdn Bhd
Lot 3 & 5, Jalan Tandang
46050 Petaling Jaya
Selangor, Malaysia

Date of revision

08/09/2015

Serial Number

BPFK(R4/1)080915/00306