Stugeron[®] 15 mg tablets

Cinnarizine

Stugeron is a registered trademark

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1 What Stugeron tablets are and what they are used for

The name of your medicine is Stugeron 15 mg tablets. It is called Stugeron tablets in this leaflet. The tablets contain a medicine called cinnarizine that helps symptoms caused by balance or movement problems.

Stugeron tablets are used:

- to control travel sickness
- for problems with balance (such as Ménières disease) to treat symptoms of:
 - feeling dizzy or lightheaded
 - ringing in the ears
 - feeling sick (nausea) and being sick (vomiting)

This medicine is for use in adults and children aged over 5 years.

How to help stop travel sickness

The following tips may help you avoid travel sickness:

- At sea
 - Stay on deck and keep your eyes on the horizon
 - Keep away from diesel and galley smells
 - Do not eat rich and fatty foods while travelling
- On the road
 - Keep looking ahead into the distance
 - Travel in daylight with a window open
 - Make sure children can see out of the windscreen
 - Do not read
 - Do not eat rich and fatty foods while travelling

2 What you need to know before you take Stugeron tablets

Do not take Stugeron tablets if:

 You are allergic to cinnarizine or any of the other ingredients in Stugeron tablets (listed in section 6 below)

• 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.

Warnings and Precautions

Check with your doctor before taking Stugeron tablets if:

- You have Parkinson's disease
- You suffer from liver or kidney problems
- You have a blood problem called 'porphyria'

You may still be able to take Stugeron tablets, but you should discuss this with your doctor first.

Other medicines and Stugeron tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription, herbal medicines, dietary supplements or vitamins.

In particular tell your doctor or pharmacist if you are taking medicines for:

- Anxiety
- Difficulty sleeping
- Pain
- Depression

Talk to your doctor before using Stugeron tablets if you are taking any of these medicines.

Skin tests

This medicine could reduce your reaction to skin tests for allergies. If you have taken Stugeron tablets in the 4 days before these tests, tell your doctor.

Stugeron tablets with alcohol

Stugeron tablets can make you drowsy. Drinking alcohol may make this worse.

Pregnancy and breast-feeding

- Do not take Stugeron tablets if you are pregnant, think you may be pregnant or might become pregnant
- Do not take Stugeron if you are breast-feeding. Ask your doctor or pharmacist for advice

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding

Driving and using machines

Stugeron tablets can make you drowsy. If this happens, do not drive or use any tools or machines.

Stugeron tablets contain lactose and sucrose.

If your doctor has told you that you are intolerant of some sugars, discuss it with them before taking this medicine.

3 How to take Stugeron tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Do not take more tablets than the doctor has told you
- Take after a meal
- Suck, chew or swallow the tablets whole with water
- Not recommended for children aged under 5 years old

3 How to take Stugeron tablets (continued)

How much to take

For travel sickness

Adults and children over 12 years old:

- 2 tablets 2 hours before travelling then
- 1 tablet every 8 hours during the journey

Children aged 5 – 12 years old:

- 1 tablet 2 hours before travelling then
- ½ a tablet every 8 hours during the journey

For problems with balance

Adults and children over 12 years old:

2 tablets 3 times a day

Children aged 5-12 years old:

1 tablet 3 times a day

If you take more Stugeron tablets than you should

If you take more Stugeron tablets than you should, talk to a doctor or go to the nearest hospital casualty department straight away.

If you forget to take Stugeron tablets

- Make sure you leave 8 hours since your last tablet before taking the missed dose
- Then keep taking your medicine as your doctor has told you
- Do not take a double dose to make up for a forgotten dose

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

4 Possible side effects

Like all medicines, Stugeron tablets can cause side effects, although not everybody gets them.

Common (affects less than 1 in 10 people)

- Drowsiness
- Feeling sick (nausea)
- Indigestion
- Weight gain

Uncommon (affects less than 1 in 100 people)

- Feeling tired
- Having stomach pain
- Being sick (vomiting)
- Increased sweating
- Skin rash (swelling, redness or itching of the skin)

Other side effects (frequency not known):

- Unusual movements, including trembling and shaking of the hands and fingers, twisting movements of the body, shuffling walk and muscle stiffness
- Yellowing of the skin or whites of the eyes (jaundice)

Other side effects that may occur with this type of medicine include allergic reactions, headache and dry mouth.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: <u>www.mhra.gov.uk/yellowcard</u> By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Stugeron tablets

- Keep this medicine out of the sight and reach of children
- Do not use Stugeron tablets after the expiry date which is stated on the label. The expiry date refers to the last day of that month
- There are no special storage conditions.
- Do not throw away any medicines via wastewater or household waste.
 Ask your pharmacist how to throw away medicines you no longer use.
 These measures will help protect the environment.

6 Contents of the pack and other information

What Stugeron tablets contain

- The active substance is cinnarizine. Each tablet contains 15 mg of cinnarizine.
- The other ingredients are lactose monohydrate, maize starch, sucrose, talc, magnesium stearate and polyvidone.

What Stugeron tablets look like and contents of the pack

Stugeron tablets are white and round with S/15 on one side and JANSSEN' on the other side.

Stugeron tablets are available in blister packs containing 100 tablets.

Marketing Authorisation Holder:

JANSSEN-CILAG LTD, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG, UK

Manufacturer:

Janssen-Cilag, Domaine de Maigremont, 27100 Val de Reuil, France

OR

McGregor Cory Limited, Middleton Close, Banbury, Oxfordshire, OX16 4RS, UK

For information in large print, tape, CD or Braille, telephone 0800 7318450.