

STUGERON FORTE

75mg tablet

CINNARIZINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 only • Do not pass it on to others • It may harm them, even if their signs of illness 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 •

What is in this leaflet?

1. What STUGERON FORTE is and what it is used for
2. Before you take STUGERON FORTE
3. How to take STUGERON FORTE
4. Possible side effects
5. How to store STUGERON FORTE
6. Further information

1. WHAT STUGERON FORTE IS AND WHAT IS IT USED FOR

Cinnarizine, the piperazine derivative is the medicine from the group of H1-receptor antagonist and a calcium channel blockers. ATC code: N07CA02.

The medicine reduces the flow of calcium ions into smooth muscle arteries and causes the expansion of blood vessels (vasodilation).

Cinnarizine is effective and reliable in the treatment of symptoms caused by the disorders of the inner ear. Since it prevents the narrowing of blood vessels (acts as an anti-vasoconstrictor), it is used to relieve symptoms caused by weaker cerebral and peripheral blood flow. It does not affect blood pressure and heart rate.

Cinnarizine is intended for:

- Treatment of balance disorders (vestibular disorders), such as dizziness, noise in the ears (tinnitus), nausea and vomiting in diseases of the inner ear that can affect one or both ears (Meniere's disease).

2. BEFORE YOU TAKE STUGERON FORTE

Do not take STUGERON FORTE

- If you are allergic to Cinnarizine, or other ingredients of this medicine
- If you have Parkinsonism (chronic, slowly progressing disease that affects the brain region responsible for deliberate movements)
- If you have extrapyramidal syndrome (movement disorders)

Take special care with STUGERON FORTE

Tell your doctor:

- If you have low blood pressure (we do not advise taking cinnarizine)
- If you are older than 65 years you may experience hypothermia (lowering of body temperature below normal), but you also may experience extrapyramidal signs (movement disorders),
- If you have porphyria (disorder in the metabolism of porphyrins).

Because the medicine can affect skin tests results (may be a false negative), discontinuation of the treatment is recommended at least four days before the test.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Simultaneous use of cinnarizine and some other medicines can lead to interaction, and therefore the effect of either medicine can be reduced or increased.

Tell your doctor or pharmacist if you are taking:

- Medicines that dilate blood vessels (vasodilators) and other medications to treat high blood pressure (other antihypertensives)
- Medicines for the treatment of nausea and vomiting that may be caused by undesirable effects of medicines or by a disease of the digestive organs (antiemetic domperidone).

The simultaneous use of alcohol, sedatives, or medicines to treat depression (tricyclic antidepressants) and cinnarizine may increase the sedative effect.

Taking STUGERON FORTE with food and drink

Take your medicine after meals with liquid.

Avoid drinking alcoholic beverages. Alcohol may increase the sedative effect of cinnarizine.

Pregnancy and breastfeeding

Talk to your doctor before taking this or any other medicine if you are pregnant.

During pregnancy and breastfeeding, avoid the application of cinnarizine.

Driving and using machines

Cinnarizine may cause drowsiness, especially at the beginning the treatment or while drinking alcohol, so we do not advise you to drive or use machines.

Important information about some of the ingredients of STUGERON FORTE

STUGERON FORTE tablets contain Lactose. If your doctor told you that you have intolerance to some sugars, consult your doctor before taking this medicine.

3. HOW TO TAKE STUGERON FORTE

Adults and elderly patients

| | |
|------------------|--------------------------------------|
| indication | The daily dosage 1 tablet = 75 mg |
| Balance disorder | 1 tablet 1 or 2 times per day |

The maximum daily dose: 3 tablets.

STUGERON FORTE 75 mg tablets are not suitable for the treatment of children.

If you take more STUGERON FORTE than you should

The first signs of overdose are drowsiness, dizziness and inconsistency of movement. serious overdose is manifested as hypothermia, skeletal muscle spasms (convulsions), vomiting, involuntary trembling or shaking (tremor), reduced blood pressure (hypotension) and disturbances of consciousness that can lead to coma and respiratory failure (respiratory depression).

If you experience signs of overdose, the doctor will take appropriate action.

If you forget to take STUGERON FORTE

If you forget to take a dose, take it as soon as you remember. Do not take a double dose next time, but continue taking the medicine as prescribed by your doctor or as indicated in the package leaflet.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

According to frequency, side effects are classified into the following groups:

Very common (occurring in more than 1 in 10 patients); common (less than 1 in 10 patients); uncommon (less than 1 in 100 patients); rare (less than 1 in 1,000 patients) and very rare (less than 1 in 10,000 patients), frequency not known.

Common side effects: dry mouth.

Uncommon side effects: nausea, vomiting, diarrhea.

Rare side effects: headache, parkinsonism, hypersensitivity reactions, excessive sensitivity to sunlight (photosensitivity), loss of appetite, weight gain, sweating, drowsiness, insomnia.

Very rare side effects: vertigo, dizziness, severe anxiety accompanied by motor restlessness (paradoxical agitation), a syndrome similar to systemic inflammatory chronic dermatosis (lupus erythematosus), fatigue, cholestatic jaundice.

Unknown side effects: depression.

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

5. HOW TO STORE STUGERON FORTE

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container and box after "EXP".

The shelf life of medicine is 5 years from the date of manufacture.

Store below 25 °C.

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.

6. FURTHER INFORMATION

What STUGERON FORTE contains

- The active substance is cinnarizine. Each tablet contains 75 mg of cinnarizine.
- The other ingredients are lactose monohydrate, corn starch, pregelatinized starch, povidone, polysorbate 20 (E432), microcrystalline cellulose (E460), anhydrous colloidal silica and magnesium stearate (E572).

What STUGERON FORTE looks like and contents of the pack

The tablets are white, round, flat, with the notched edge.
There are boxes of 50 (5 x 10) tablets in the blisters.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Krka Pharmaceuticals, dd, Šmarješka cesta 6, Novo Mesto, Slovenia R.

Manufacturer of the medicinal product:

Krka Pharmaceuticals, dd (In cooperation with Janssen Pharmaceutica, Belgium),
Šmarješka cesta 6, Novo Mesto, Slovenia R.