PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Name of the medicine, its form and strength

Stunarone® Tablets, 25 mg

Active ingredient and its quantity in each tablet:
Cinnarizine 25 mg

For the list of inactive and allergenic ingredients in the preparation: See in section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Stunarone is used to treat the symptoms of nausea and dizziness caused by Ménière's disease and other disturbances associated with the vestibula and motion sickness.

Therapeutic group: Anti-vertigo

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine, listed in section 6 "Further information".

Special warnings regarding use of the medicine:
Before beginning treatment with Stunarone, tell the doctor if:

- You suffer from Parkinson's disease. Inform your doctor, who will then decide whether you should take Stunarone.
- You are using any other drugs. Please also read the section "Drug interactions".
- You have a disorder in the formation of hemoglobin (porphyria). Your doctor will consult a medical specialist.

Children and adolescents:
The medicine is not intended for children under 5 years of age.

Drug interactions:
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, if you are taking:
Medicines to treat depression and medicines that slow down your reaction time (e.g.,

hypnotics, sedatives and strong analgesics); their sedative effects may be increased when concomitantly given with Stunarone.

Use of the medicine and food:
Swallow the tablet after a meal. It is recommended to take it with a glass of water.

Use of the medicine and alcohol consumption:
A combination of Stunarone and alcohol increases the sedative effect of each one; therefore, do not drink alcohol during the course of treatment with Stunarone.

Pregnancy, breastfeeding and fertility:
Pregnancy:
If you are pregnant, may be pregnant or are trying to become pregnant, consult the doctor before using the medicine. The doctor will decide whether you should take Stunarone.
Breastfeeding:
If you are taking Stunarone, do not breastfeed since very small amounts of the medicine may be excreted in the breast milk.
Fertility:
There are no data available on the effect of Stunarone on fertility in humans.

Driving and operating machinery:
Especially at the start of treatment, Stunarone may cause drowsiness and thus impair the ability to react and your ability to drive a vehicle. You should be cautious when operating machinery and when engaging in any activity which requires alertness. Children should be cautioned against riding a bicycle or playing near the road, and the like.

Important information about some of the ingredients of the medicine:
The tablets contain sucrose and lactose monohydrate. If your doctor has told you that you are suffering from an intolerance to certain sugars, consult with the doctor before commencing treatment with the medicine.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and the treatment regimen will be determined by the doctor only. The recommended dosage in adults suffering from balance disorders is generally one 25 mg tablet, 3 times a day.
The recommended dosage in adults suffering from motion sickness is generally one 25 mg tablet, half an hour before traveling; the dose should be repeated every 6 hours.
In children (5-12), it is recommended to take half of the adult dosage.
Do not exceed the recommended dose.

Method of administration – swallow the tablet after a meal. It is recommended to take it with a glass of water.
The tablet can be halved to ease administration, but not for taking a partial dose. Please use a tablet splitter to halve the tablet.
There is no information about crushing/chewing.

If you accidentally took a higher dosage, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.
Too high a dose of Stunarone Tablets may be manifested by the following signs and symptoms: alterations in consciousness, ranging from sleepiness to loss of consciousness and coma, vomiting, muscle weakness or lack of coordination and seizures. Death has been reported in association with cinnarizine overdose. **If you suspect that you took an overdose, refer immediately to the doctor.**

If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.
Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Stunarone may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Common side effects – effects occurring in 1-10 in 100 users:
- Sleepiness
- Weight gain
- Nausea

Uncommon side effects – effects occurring in 1-10 in 1,000 users:
- Longer than usual nocturnal sleep
- Vomiting
- Excessive sweating
- Fatigue
- Appearance of red and itchy round lesions or itchy rash on the skin or appearance of gray-white spots inside the mouth

Rare side effects – effects occurring in 1-10 in 10,000 users:
- Upper abdominal pain, indigestion

Side effects of unknown frequency (effects whose frequency has not been determined):

- Movement problems, such as jerky movements, muscle stiffness, trembling – these effects are known as extrapyramidal effects
- Liver problems that cause yellowing of the skin or eyes (jaundice)
- Appearance of red round lesions on the skin or rash that appears on sun-exposed skin areas

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting of side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:
Store below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Lactose monohydrate, maize starch, sucrose, talc, cottonseed oil hydrogenated, polyvidone K90

What the medicine looks like and the contents of the pack –
A circular, biconvex, white tablet with a score line, inscripted with JANSSEN on one side and S/25 on the other side.
The tablets are packaged in a blister. Each package contains 25 tablets.

Manufacturer: Janssen Cilag S.p.A. Via C. Janssen 04100, Borgo S. Michele, Latina

Registration Holder and Address: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Revised in July 2025.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 031-26-21879.

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