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

Inactive and allergenic ingredients: See section "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.
- irritation and circulation disturbances of the inner ear (ringing in the ears, dizziness, rapid and involuntary eye movement and nausea, sweating and vomiting associated with it).
- Ménière's disease.

In addition, Stunarone is also used to prevent motion sickness.

Therapeutic group: Anti-vertigo

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- In patients suffering from depression and in patients suffering from, or have previously suffered from, Parkinson's disease.
- 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".
- You recently had a heart attack.
- The medicine is not intended for children under 5 years
- Prolonged use should only be under medical supervision.

Special warnings regarding use of the medicine

- Before beginning treatment with Stunarone, tell the doctor if:

 You have Parkinson's disease; Only give Stunarone if the benefit outweighs the possible risk of worsening of the disease
- · Inform the doctor and pharmacist of any other ailment or allergy.

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 responsiveness (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, with a beverage of some kind.

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:

If you are pregnant, may be pregnant or are trying to become pregnant, consult the doctor before using the medicine. Only use Stunarone during pregnancy on explicit instruction from the doctor.

If you are breastfeeding, do not use the medicine.

As it is not known whether Stunarone is secreted into breast milk, this medicine should not be used during breastfeeding.

Driving and operating machinery:

Use of this medicine may, especially at the start of treatment, cause drowsiness and thus impair the ability to react and therefore, caution must be exercised when driving a car, operating dangerous 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 and the like.

Important information about some of the ingredients the medicine

The tablets contain sucrose and lactose. If your doctor has told you that you are suffering from intolerance to certain sugars, consult with the doctor before commencing treatment with the medicine.

Each tablet contains: 158.8 mg lactose monohydrate and 15 mg sucrose, which must be taken into consideration in diabetic patients.

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.

Do not exceed the recommended dosage.

Method of administration – swallow the tablet after a meal, with a beverage of some kind.

Do not change the prescribed dosage at your own discretion. If you think that the effect of the medicine is too weak or too strong, report to the doctor or pharmacist.

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.

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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, low blood pressure. 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

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 <u>each time</u> 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 by the list of side effects. You may not suffer from any of them.

Side effects which require special attention:

An allergic reaction, manifested by swelling of the face or throat. Hives, irritation, redness or blistering of the skin. Refer to a doctor as soon as possible.

Common side effects – effects occurring in 1-10 in 100 users

- Sleepiness
- Weight gain

Uncommon side effects – effects occurring in 1-10 in 1,000

- Longer than usual nocturnal sleep
- Vomiting
- Excessive sweating
- Tiredness
- 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

Very rare side effects – effects occurring in less than 1 user in 10,000

- 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.

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, su cottonseed oil hydrogenated, polyvidone K90 sucrose, talc,

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

Revised in February 2021 according to MOHs guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 312621879.