Patient Package leaflet in accordance with the Pharmacists 'Regulations (Preparations) 1986
The dispensing of this medicine requires a physician's prescription

Raxone Idebenone

Film-coated tablets

Composition :
Active ingredient:
Idebenone 150 mg
Each tablet contains 48 mg lactose

For the complete list of the inactive ingredients and allergic substances, please see section" 2 Important information about some of the drug ingredients "and section 6" Additional Information."
Read the entire leaflet carefully before using this medicine . This leaflet contains concise information about the medicine. If you have further questions, please consult your physician or pharmacist.
This medicine has been prescribed for the treatment of your condition; do not pass it on to others. It may harm them even if you think their medical condition is similar to yours.

This medicine is intended for adults and adolescents over the age of 12.

1.What is this medicine intended for?

Raxone Idebenone contains an active substance called Idebenone. Idebenone is intended for the treatment of visual impairment in adolescents and adults with Leber's Hereditary Optic Neuropathy (LHON).

Therapeutic group : This medicine affects the nervous system.

LHON is a hereditary disease that passes in the family from one generation to another.
This disease is caused by a mutation that affects the ability of eye cells to produce the energy they need in order to function properly, which causes these cells not to function.
This disease may cause vision loss due to the inactivity of the eye cells responsible for vision .

Treatment with **Raxone Idebenone** may restore the activity of energy-producing eye cells, which enables inactive cells to function again and improve vision .

2.Before using this medicine

Do not use the medicine if:

You are sensitive (allergic) to the active substance Idebenone or to any of the other ingredients this medicine contains (please see section 6 "Additional Information").

Special warnings regarding the use of this medicine

Prior to treatment with Raxone Idebenone, tell your physician if:

- You suffer from blood, liver, or kidney problems.

Change in urine color

Raxone Idebenone may cause the color of your urine to become reddish brown. This change in color is harmless and does not mean your treatment with **Raxone Idebenone** needs to change.
However, the change in color could mean that you have problems with your kidneys or bladder .

- Inform your physician if you notice the color of your urine changes.
- Your physician may perform a urine test to make sure the change in the color of your urine does not indicate you have other problems.

Children and adolescents
This medicine must not be used in children under the age of 12 because it is unknown if **Raxone Idebenone** is effective and safe for use in children under 12.

Tests/examinations and follow-up
Your physician will examine your vision prior to and during treatment.

Drug Interactions:
If you are taking or have recently taken other medicines, including over-the-counter medicines and nutritional supplements, tell your physician or pharmacist . This applies in particular if you are taking:

- Antihistamines for the treatment of allergies, such as: Astemizole, Terfenadine
- Medicines for the treatment of heartburn, such as: Cisapride
- Medicines for the treatment of Tourette syndrome manifested by muscle and speech tics, such as: Pimozide
- Medicines for the treatment of heart rhythm disorders, such as: Quinidine
- Medicines for the treatment of migraine, such as: Dihydroergotamine, Ergotamine
- Medicines used for anesthesia or numbing purposes, called“ anaesthetics ,”such as: Alfentanil
- Medicines for the treatment of rheumatoid arthritis and psoriasis, such as: Cyclosporine
- Medicines intended to prevent the body from rejecting transplanted organs, such as: Sirolimus, Tacrolimus
- Opioid medicines for strong pain relief, such as: Fentanyl

Use of the medicine and food
Raxone Idebenone should be taken with food to assist the absorption of the medicine from the stomach into the bloodstream.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you might be pregnant, or are planning to become pregnant, consult your physician before using **Raxone Idebenone.**

- Your physician will offer guidance regarding treatment with **Raxone Idebenone** to you only if the benefits of the treatment outweigh the risks to the fetus .
- **Raxone Idebenone** may pass into the mother’s milk. If you are breastfeeding, consult your physician on whether you should stop breastfeeding or discontinue treatment with **Raxone Idebenone** .Your physician will weigh the benefit of breastfeeding a child against the benefit of treatment with **Raxone Idebenone** for you.

Driving and using machines

Using **Raxone Idebenone** is not expected to affect your ability to drive or use machines .

Important information about some of the ingredients of the medicine

- **Raxone Idebenone** contains Lactose (a type of sugar). If you have been told by your physician that you have lactose intolerance or that you cannot digest certain types of sugar, consult your physician before using **Raxone Idebenone**.
- **Raxone Idebenone** contains a colorant called“ sunset yellow ”(also called E110), which may cause an allergic reaction.

3.<u>How should this medicine be used?</u>

Always use according to your physician’s instructions. If you are not sure, consult your physician or pharmacist.

The dose and treatment method will be determined only by your physician. The standard dose is usually 2 tablets 3 times a day, in total 6 tablets a day.

Do not exceed the recommended dose.

Method of Administration

- Swallow the medicine with food to improve the absorption of the medicine from the stomach into the bloodstream.
- The tablet should be swallowed whole with a glass of water .
- Do not crush or chew the tablet.
- The tablets should be taken at the same time every day. For example, in the morning with breakfast, at noon with lunch, in the evening with dinner.

If you have mistakenly taken an overdose or if a child has accidently swallowed the medicine, refer immediately to a physician or the hospital's emergency room and bring the package of the medicine with you.

If you forget to take the medicine at the required time, please skip the missed dose. Take the next dose at the usual time and consult your physician. Do not take a double dose to make up for the missed dose.

Always take your treatment regularly as recommended by your physician.

Even if there is an improvement in your health condition, do not discontinue treatment with the medicine without consulting the physician.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take your medicines. Wear glasses if you need them.

If you have any further questions about the use of the medicine, consult your physician or pharmacist.

4.<u>Side effects</u>

As with any medicine, using **Raxone Idebenone** may cause side effects in some users. Do not be alarmed by the list of side effects. You might not suffer from any of them. The following side effects may occur with this medicine:

<u>Very common side effects, which appear in more than 1 of every 10 users :</u>

- Nasopharyngitis (inflammation in the area of the nose and the upper pharynx - common cold)
- Cough

<u>Common side effects, which appear in 1-10 of every 100 users :</u>

- Diarrhea (mild to moderate, which usually does not require discontinuation of treatment)
- Back pain

<u>Side effects of unknown frequency (cannot be deduced from existing data):</u>

- Bronchitis
- Changes in blood test results: Low white-blood-cell count, low red-blood-cell count, low platelet count
- Increase in cholesterol or blood lipid level seen in blood tests.
- Fits, feeling confused, hallucinations (seeing or hearing things that do not exist), feeling excited, uncontrolled movements, a tendency to wonder away, feeling dizzy, headache, feeling restless, dazed and unable to act or think normally.
- Nausea, vomiting, loss of appetite, indigestion
- High levels of liver enzymes seen in blood tests - which indicates liver problems. In addition, high levels of blood Bilirubin, which might make your skin and the whites of your eyes look yellow, liver inflammation (hepatitis)
- Rash, itching
- Pain in the extremities
- High levels of blood Nitrogen, which also affects the color in urine
- Generally feeling unwell

If you develop a side effect, if one of your side effects becomes worse, or if you develop a side effect not mentioned in this leaflet, consult your physician.

Side effects can be reported to the Ministry of Health by clicking on the link Reporting Side Effects from Drug Treatment, which appears on the homepage of the Ministry of Health website (www.health.gov.il) and directs to an online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5.<u>How should the medicine be stored?</u>

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants to prevent poisoning. Do not induce vomiting without explicit instruction from your physician
- Do not use the medicine after the expiry date, which appears on the external package and the bottle. The expiry date refers to the last day of that month.

- Do not dispose of medicines in the sewage or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

Storage conditions:

- Store below 30°C.
- After opening, it can be used until the expiry date noted on the package.

6.Additional information

- In addition to the active substance idebenone, this medicine also contains : Cellulose, microcrystalline, lactose monohydrate, croscarmellose sodium, povidone K25, Silica colloidal anhydrous and magnesium stearate
- Tablet film coating: Poly (vinyl alcohol), macrogol 3350, titanium dioxide, talc, sunset yellow (E110)
- What does the medicine look like and what is the content of the package: Orange, film-coated, round tablets of 10 mm diameter, engraved with' Santhera 'on one side and '150' on the other side .

  Supplied in white plastic bottles; each bottle contains 180 tablets
- **Name and address of manufacturer :**Santhera Pharmaceuticals (Switzerland) AG., Pratteln, Switzerland.
- **Name and address of license holder :**Megapharm Ltd., 15 HaTid'har Street, Ra'anana, Israel.
- Updated in September 2023 according to Ministry of Health guidelines.
- Drug registration number in the National Drug Registry at the Ministry of Health is 159-18-34904.