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ITEM CHIESI

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**Package leaflet: information for the user**

## Raxone 150 mg film-coated tablets idebenone

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**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. See section 4.

**What is in this leaflet**

1. What Raxone is and what it is used for
2. What you need to know before you take Raxone
3. How to take Raxone
4. Possible side effects
5. How to store Raxone
6. Contents of the pack and other information

**1. What Raxone is and what it is used for**

Raxone contains a substance called idebenone.

Idebenone is used to treat vision impairment in adults and adolescents with an eye disease called Leber's Hereditary Optic Neuropathy (LHON).

- This eye problem is inherited – this means it runs in families.
- It is caused by a problem with your genes (called a "genetic mutation") that affects the ability of cells in the eye to produce the energy they need to work normally, so they become inactive.
- LHON can lead to loss of eyesight due to the inactivity of cells responsible for vision.

Treatment with Raxone can restore the ability of cells to produce energy and so allow inactive eye cells to work again. This can lead to some improvement in lost eyesight.

**2. What you need to know before you take Raxone****Do not take Raxone**

- if you are allergic to idebenone or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Raxone if:

- you have any blood, liver or kidney problems.

**Change in urine colour**

Raxone may make your urine become reddish brown.

This change in colour is harmless – it does not mean your treatment needs to change. However, the change in colour could mean that you have problems with your kidneys or bladder.

- Tell your doctor if your urine changes colour.
- He or she may do a urine check to make sure the change in colour is not hiding other problems.

**Tests**

Your doctor will check your eye-sight before you start taking this medicine and then at regular visits while you are taking it.

**Children and adolescents**

This medicine should not be used in children. This is because it is not known if Raxone is safe or works in patients under 12 years of age.

**Other medicines and Raxone**

Some medicines may interact with Raxone. Tell your doctor if you are taking, have recently taken or might take any other medicines, especially any of the following:

- antihistamines to treat allergies (astemizole, terfenadine)
- to treat heartburn (cisapride)
- to treat muscle and speech tics associated with Tourette syndrome (pimozide)
- to treat heart rhythm disorders (quinidine)
- to treat migraine (dihydroergotamine, ergotamine)
- to put you to sleep called "anaesthetics" (alfentanil)
- to treat inflammation in rheumatoid arthritis and psoriasis (cyclosporine)
- to prevent the rejection of an organ transplant (sirolimus, tacrolimus)
- to treat strong pain called "opioids" (fentanyl)

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

- Your doctor will prescribe Raxone to you only if the benefits of the treatment are greater than the risks to the unborn child.
- Raxone may pass into the mother's milk. If you are breast-feeding your doctor will discuss with you whether to stop breast-feeding or to stop taking the medicine. This will take into account the benefit of breast-feeding to the child and the benefit of the medicine for you.

**Driving and using machines**

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

**Raxone contains lactose and sunset yellow (E110)**

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Raxone contains a colourant called "sunset yellow" (also called E110). This may cause allergic reactions.

**3. How to take Raxone**

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

**How much to take**

The recommended dose is 2 tablets three times a day – this is a total of 6 tablets per day.

**Taking this medicine**

- Take the tablets with food – this helps to get more of the medicine from your stomach into your blood.
- Swallow the tablets whole with a glass of liquid.
- Do not crush or chew the tablets.
- Take the tablets at the same time of day each day. For example in the morning at breakfast, with lunch at mid-day and with dinner in the evening.

**If you take more Raxone than you should**

If you take more Raxone than you should, talk to your doctor straight away.

**If you forget to take Raxone**

If you forget a dose, skip the missed dose. Take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Raxone**

Talk to your doctor before you stop taking this medicine.

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

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effect may happen with this medicine:

**Very common** (may affect more than 1 in 10 people):

- nasopharyngitis (cold)
- cough

**Common** (may affect up to 1 in 10 people):

- diarrhoea (mild to moderate that usually does not require discontinuation of treatment)
- back pain

**Unknown frequency** (frequency cannot be estimated from the available data):

- bronchitis
- changes in blood test results: low level of white blood cells, or low level of red blood cells, or low level of platelets
- increased cholesterol or fat in the blood – shown in tests
- fits, feeling confused, seeing or hearing things that are not real (hallucinations), feeling excited, movements that you cannot control, a tendency to wander away, feeling dizzy, headache, feeling restless, dazed and unable to act or think normally
- nausea, vomiting, loss of appetite, indigestion
- high levels of some liver enzymes in the body which mean you have liver problems – shown in tests, high levels of "bilirubin" – this can make your skin and the whites of your eyes look yellow, hepatitis
- rash, itching
- pain in extremity
- high levels of nitrogen in the blood – shown in tests change in urine colour
- generally feeling unwell

**Reporting of side effects**

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA

Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Raxone**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the bottle after 'EXP'. The expiry date refers to the last day of that month.

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 Raxone contains**

- The active substance is idebenone. Each film-coated tablet contains 150 mg of idebenone.
- The other ingredients are:  
Tablet core: lactose monohydrate, cellulose microcrystalline, croscarmellose sodium, povidone K25, magnesium stearate and silica colloidal anhydrous.  
Tablet film-coating: macrogol, poly(vinyl alcohol), talc, titanium dioxide, sunset yellow (E110).

**What Raxone looks like and contents of the pack**

- Raxone film-coated tablets are orange, round tablets of 10 mm diameter, engraved with the Santhera logo on one side and '150' on the other side.
- Raxone is supplied in white plastic bottles. Each bottle contains 180 tablets.

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**Is this leaflet hard to see or read?**

**Phone 0161 488 5555 for help.**

**This leaflet was last revised in 10/2022**

This medicinal product has been authorised under 'exceptional circumstances'.

This means that due to the rarity of the disease it has not been possible to obtain complete information on this medicinal product.

The European Medicines Agency will review any new information which may become available every year and this leaflet will be updated as necessary.

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>. There are also links to other websites about rare diseases and treatments.

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