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

The medicine is dispensed with a doctor's prescription only

Remotiv® 250
Remotiv® 500
Film-coated tablets

Active ingredient:
Each tablet of Remotiv 250 contains:
250 mg dry extract of the Hypericum plant (St. John's wort).
Each tablet of Remotiv 500 contains:
500 mg dry extract of the Hypericum plant (St. John's wort).

The special extract, called Ze117, is produced via a unique patented extraction process.
The extract in a Remotiv 250 tablet contains (amongst the other ingredients) 0.5 mg hypericin.
The extract in a Remotiv 500 tablet contains (amongst the other ingredients) 1 mg hypericin.
The extract may contain a minuscule amount of hyperforin.
For a list of the inactive ingredients see section 6. See also "Important information about some of the medicine's ingredients" in section 2.

Read the entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for 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?
Remotiv relieves symptoms of mild to moderate depression, accompanied by anxiety, states of tension, inner restlessness, dejected mood, mood fluctuations, difficulty falling asleep or difficulty sleeping through the night.

Therapeutic class:
Plant-derived natural antidepressant.

2. Before using the medicine
Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients the medicine contains (for the list of inactive ingredients, see section 6).
- You are taking an antidepressant (of any type) or any other medicine with a serotonergic activity.
- You suffer or have suffered in the past from sensitivity to light, including sunlight.
- In children under the age of 6.

Special warnings regarding the use of the medicine:
- Antidepressants increase the risk of suicidal behavior and thoughts. If you notice behavioral changes (worsening of depression, suicidal thoughts and the like), refer to the doctor immediately.
- Do not use this medicine for a prolonged period without consulting the doctor.
- If you are about to undergo a photodynamic diagnosis or therapy (using light), or if you are about to undergo surgery, inform the attending doctor and/or the anesthesiologist that you are taking this medicine. Stop taking Remotiv at least 5 days before surgeries. You can take the medicine again only after consulting the attending doctor.
- During the treatment with Remotiv, the skin and eyes should be protected from exposure to the sun. In rare cases, especially in fair-skinned people, there may be side effects in the eyes or skin (for example, redness similar to sunburn) after taking Remotiv and exposure to the sun. If this happens, stop the treatment and avoid exposure to the sun (or to other UV radiation) for about two weeks.
- During the treatment, avoid visiting a solarium or tanning salons.
- If you are sensitive to any type of food or medicine, inform your doctor before taking the medicine.

Before treatment with Remotiv tell the doctor: if you suffer from other diseases, or if you have suffered in the past from impaired function of the liver, kidneys/ urinary system.

Drug interactions:
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially inform the doctor or pharmacist if you are taking the following medicines (please note that the following list indicates the names of the active ingredients in the medicines. If you are not sure whether you are using any of these medicines, please consult the doctor or pharmacist):
- Antidepressants and serotonergic medicines such as: amitriptyline, fluoxetine, buspirone, triptans and more.

Use of the medicine and food:
It is advisable to take the medicine with or after a meal.

Pregnancy and breastfeeding:
Using the medicine is not recommended during pregnancy and breastfeeding. If you are pregnant, trying to become pregnant or breastfeeding, consult the doctor.

Driving and use of machinery:
The use of this medicine may cause side effects, such as dizziness. If you experience dizziness or effects that may affect driving or operating machinery – you should exercise caution when driving a vehicle, operating dangerous machinery and with any activity requiring alertness.

Use in children:
The medicine should not be used in children under the age of 6. This medicine is usually not intended for children under the age of 12.

Important information about some of the medicine's ingredients:
Remotiv 250 tablets contain lactose. If you are sensitive to lactose, inform the doctor before taking this medicine (see section 6).
Each Remotiv tablet contains less than 1 mmol (23 mg) sodium, and is therefore essentially considered sodium free.
Each Remotiv tablet contains about 120 mg carbohydrates and is permitted for diabetics.

3. How to use the medicine?
Always use according to the doctor's instructions. If you are uncertain about the dosage and manner of treatment with the medicine, check with the doctor or pharmacist.
The dosage and treatment regimen will be determined only by the doctor.

Dosage in the absence of other instructions from the doctor:
Remotiv 250: one tablet twice daily (morning and evening).
Remotiv 500: one tablet once daily (morning or evening).
Do not exceed the recommended dose.
This medicine should be used at set intervals as determined by the attending doctor.
The effect of the medicine is expected to start within 14 days.
Do not chew or crush the tablet! Do not halve the tablet, as it does not have a score line.
Swallow the tablet with some water. It is advisable to take the medicine with or after a meal.

If you accidentally took a higher dosage:
If you took an overdose or if a child accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the medicine package with you.
Adhere to the treatment as recommended by the doctor. Even if there is an improvement in your state of health, do not stop treatment with the medicine without consulting a doctor.
Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.
If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects
As with any medicine, using Remotiv may cause side effects in some users. If the side effects persist, are bothersome or if they worsen, consult the doctor. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
Discontinue treatment and refer to a doctor immediately if you experience redness of the skin and/or sensitivity of the eyes and skin to the sun (such as sunburn, photosensitivity) (rare). See also "Special warnings regarding the use of the medicine".

Additional side effects:

Common side effects (occur in 1-10 out of 100 users):
Gastrointestinal problems (such as abdominal pain), headache, sweating, weakness.

Uncommon side effects (occur in less than 1 out of 100 users):
Dizziness, tiredness, restlessness, rash.

Rare side effects (occur in 1-10 out of 10,000 users):
Sensitivity of the eyes and skin to the sun.

Side effects with unknown frequency (effects whose frequency has not yet been determined):
Mania, dry mouth. In one case where a significant overdose was taken, seizures and confusion were reported.

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

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which leads to the online form for reporting side effects, or by clicking on the link:
https://sideeffects.health.gov.il/

5. How to store the medicine?
Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store in the original package below 25°C.

6. Additional information
In addition to the active ingredient, the tablets also contain the following inactive ingredients:
- Each tablet of Remotiv 250 contains: Microcrystalline cellulose, lactose monohydrate, macrogol 6000, magnesium stearate, colloidal anhydrous silica, macrogol 400, macrogol 20000, propylene glycol, hypromellose, iron oxide red (E172), titanium dioxide (E171).
  Each tablet of Remotiv 250 contains about 120 mg lactose.
- Each tablet of Remotiv 500 contains: Microcrystalline cellulose, croscarmellose sodium, macrogol 6000, magnesium stearate, colloidal anhydrous silica, macrogol 20000, stearic acid, hypromellose, iron oxide red (E172), titanium dioxide (E171).

What does the medicine look like and what does the package contain?
Remotiv 250: pink round tablets. 60 tablets in blister packs.
Remotiv 500: pink oblong tablets. 30 tablets in blister packs.

Registration Holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301
Manufacturer: Max Zeller Söhne AG, Switzerland.

Medicine registration number in the national medicines registry of the Ministry of Health:
Remotiv 250: 130 71 30720
Remotiv 500: 141 28 31607

Revised in September 2024.

194511 511010-MZ