PATIENT PACKAGE INSERT 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 through a unique, patent-protected extraction process.
The extract in a Remotiv 250 tablet contains (among the other ingredients) 0.5 mg hypericin.
The extract in a Remotiv 500 tablet contains (among the other ingredients) 1 mg hypericin.
The extract may contain a miniscule amount of hyperforin.

For the 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, please refer to the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think their medical condition is similar to yours.

1. What is the medicine intended for?

Remotiv relieves symptoms of mild to moderate depression, accompanied by anxiety, states of tension, inner restlessness, dejected moods, mood fluctuations, difficulties falling asleep or difficulty sleeping through the night.

Therapeutic group:

Natural plant-based antidepressant.

2. Before using the medicine

Do not use the medicine if:

- If you are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (for the list of the inactive ingredients, see section 6).
- If you are taking an antidepressant (of any kind) or any other medicine with serotonergic activity.
- If 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:

- Do not use this medicine for a prolonged period without consulting a doctor.
- If you are about to undergo photodynamic diagnosis or treatment (via 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. It can be taken again only after consultation with the attending doctor.
- During the treatment with Remotiv, protect your skin and eyes from exposure to the sun. In rare cases, especially in fair-skinned people, side effects may occur in the eyes or the skin (e.g. sunburn-like reddening) after taking Remotiv and sunlight exposure. In this case -

discontinue the treatment and avoid exposure to sunlight (or other UV radiation) for approximately two weeks.
- During the treatment avoid visiting a solarium or tanning salons.
- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.

Before treatment with Remotiv tell the doctor: If you suffer from other illnesses, or you have suffered in the past from impaired liver, kidney/urinary system function.

Drug interactions: If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell the doctor or pharmacist.
Especially inform the doctor or pharmacist if you are taking the following medicines (it should be noted that the following list indicates the active ingredients in the medicines. If you are not sure whether you are using one of these medicines, please consult with the doctor or pharmacist):

- Antidepressants and serotoninergic medicines such as: amitriptyline, fluoxetine, buspirone, triptans and others.).

Use of the medicine and food: recommended to take the medicine with or after a meal.

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

Driving and use of machinery: the use of this medicine may cause side effects such as dizziness. If you feel dizziness or effects that could affect driving or operating machinery - employ caution when driving a vehicle, operating dangerous machinery and in any activity requiring alertness.

Use in children: Do not use the medicine in children under the age of 6. This medicine is not generally 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 23 mg sodium and therefore can be considered almost 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. Check with the doctor or pharmacist if you are not sure.

The dosage and manner of treatment will be determined by the doctor only.

Dosage in the absence of other instructions from the doctor:

Remotiv 250: one tablet twice daily (morning and evening).

Remotiv 500: one tablet per day (morning or evening).

Do not exceed the recommended dosage.

Use this medicine at set times as determined by the attending doctor.

The effect of the medicine is expected to begin within 14 days.

Do not chew or crush the tablet! Do not halve the tablet since there is no scored line. Swallow the tablet with a little water. Recommended to take the medicine with or after a meal.

If you have accidentally taken a higher dosage: if you have taken an overdose or if a child has 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 each time you take a medicine. Wear glasses if you need them.
If you have further questions concerning the use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of Remotiv may cause side effects in some users. If the side effects persist or are bothersome or get worse, please consult the doctor. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
Discontinue the treatment and refer to the doctor upon the appearance of skin reddening, eye and skin sensitivity to sunlight (like sunburn), photosensitivity (rare). See also 'Special warnings regarding the use of the medicine'.

Additional side effects:
Common side effects (appear in 1-10 users out of 100): gastrointestinal problems (e.g. abdominal pain), headache, sweating, weakness.
Uncommon side effects (appear in less than 1 out of 100 users): dizziness, tiredness, restlessness, rash.
Rare side effects (appear in 1-10 out of 10,000 users): sensitivity of the eyes and skin to sunlight.

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

If a side effect appears, 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 on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be stored in a safe place out of the reach and sight of children and/or babies, 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) 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 approximately 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: round pink tablets. 60 tablets in blister packs.
Remotiv 500: elongated pink tablets. 30 tablets in blister packs.

Registration holder: Rafa Laboratories Ltd., PO 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

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