

Patient Leaflet According to the Pharmacists' Regulations (Preparations) - 1986

This medicine is sold 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 plant Hypericum (St. John's Wort).

Each tablet of **Remotiv 500** contains: 500 mg dry extract of the plant Hypericum (St. John's Wort).

The special extract, called Ze117, is produced via a unique, patented extraction process. The extract in a tablet of Remotiv 250 contains (among other ingredients) 0.5 mg of hypericin.

The extract in a tablet of Remotiv 500 contains (among other ingredients) 1 mg of hypericin. The extract may contain a minuscule amount of hyperforin.

For a list of inactive ingredients, please see section 6. Also see 'Important information about some of the medicine's ingredients' in section 2.

Read this entire leaflet carefully before using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or 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 to yours.

1. What is the medicine intended for?

Remotiv alleviates symptoms of mild to moderate depression, accompanied by anxiety, states of tension, restlessness or irritability, dejected mood, mood changes, difficulty in falling asleep or difficulty sleeping through the night.

Therapeutic group:

Natural anti-depressant from a plant source.

2. Before you take the medicine

Do not use this medicine if:

- Do not use if you are sensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine (for a list of inactive ingredients, please see section 6).
- Do not use this medicine if you are taking immunosuppressant medicines (e.g. cyclosporine, tacrolimus, sirolimus), medicines against the HIV virus/AIDS (e.g. nevirapine, indinavir), anticoagulants of the coumarin group (e.g. warfarin), chemotherapy medicines (e.g. irinotecan, imatinib).
- Do not use this medicine if you suffer or have suffered in the past from light sensitivity, including sun light.
- Do not use in children under 6 years of age.

Special warnings regarding the use of this medicine:

- Do not use this medicine for a prolonged period without consulting your doctor.
- If you are about to undergo a photodynamic diagnostic procedure or therapy (based on light), or if you are about to undergo surgery, inform the attending doctor and/or anaesthesiologist that you are taking this medicine.
- During treatment with Remotiv, your skin and eyes should be protected from sun exposure. Rarely, especially in people with fair skin, side effects of the eyes or skin (e.g. redness similar to sunburn) may appear after taking Remotiv and exposure to the sun. In this case – stop the treatment and avoid sun exposure (or other UV radiation) for approximately 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 this medicine.

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

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list mentions the active ingredients of the medicines. If you are unsure whether you are using one of these medicines, please consult with your doctor or pharmacist):

- Antidepressants (e.g. buspirone and medicines of the selective serotonin reuptake inhibitors group - SSRIs).
- Hormonal contraceptives (e.g. birth control pills, transdermal patches, intrauterine devices).
- Medicines of the benzodiazepine group (used, among other things, for sedation and/or for sleep), methadone.
- Medicines for reducing cholesterol of the statin group (e.g. simvastatin, atorvastatin).
- Medicines of the serotonergic group (e.g. medicines for the treatment of migraines).
- Medicines for the treatment of epilepsy.
- Steroidal hormones, digoxin.
- Do not take Remotiv if you are taking the following medicines: anticoagulants of the coumarin group (e.g. warfarin), immunosuppressant medicines (e.g. cyclosporine, tacrolimus, sirolimus) medicines against the HIV virus/AIDS, chemotherapy medicines (e.g. irinotecan, imatinib) - See section "Do not use this medicine if".

Use of this medicine and food: It is recommended to take this medicine with a meal or after it.

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

Driving and use of machinery: The use of this medicine may cause side effects such as dizziness. If you experience dizziness or other effects that may affect driving or operating machinery- caution should be taken while driving a vehicle, operating dangerous machinery and any other activity that requires alertness.

Use in children: Do not use this medicine in children under 6 years of age. This medicine is usually not intended for children under 12 years of age.

Important information about some of the medicine's ingredients: Remotiv 250 tablets contain lactose. If you are sensitive to lactose, inform your doctor before taking this medicine (see section 6).

3. How to use this medicine?

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure.

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

Recommended dosage unless otherwise instructed by your doctor:

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

Remotiv 500: one tablet once daily (in the morning or in the evening).

Do not exceed the recommended dose.

The medicine should be used at set intervals, 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. The medicine should preferably be taken with a meal or after it.

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 package of the medicine with you.

Continue with the treatment as recommended by your doctor. Even if your medical condition improves, do not stop the treatment with this medicine without consulting your 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 any further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. Side effects:

Like any medicine, the use of Remotiv may cause side effects in some users. If these side effects persist or if they are bothersome or get worse, consult your doctor. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Stop the treatment and refer to your doctor immediately upon the appearance of skin redness, sensitivity of the eyes and skin to the sun (e.g. sunburn), photosensitivity (rare). Also see 'Special warnings regarding the use of this medicine'.

Additional side effects:

Common side effects (appear in 1-10 users out of 100): digestive system problems (e.g. abdominal pain), headache, sweating, weakness.

Uncommon side effects (appear in less than 1 out of 100 users): dizziness.

Side effects with an unknown frequency: mania, restlessness, rash, dry mouth. In any case you experience side effects that are not mentioned in this leaflet, or if there is a change in your general feeling, consult your doctor immediately!

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 of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a 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, macrogol 400, macrogol 20000, propylene glycol, hypromellose, iron oxide red (E172), titanium dioxide (E171). Each tablet of Remotiv 250 contains approximately 120 mg of 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 colored tablets. 60 tablets in blisters.

Remotiv 500: elongated pink colored tablets. 30 tablets in blisters.

Registration holder: Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301

Manufacturer: Max Zeller Söhne AG, Switzerland.

Medicine registration number in the National Medicine Registry of the Ministry of Health:

Remotiv 250: 130 71 30720 **Remotiv 500:** 141 28 31607

This leaflet was checked and approved by the Ministry of Health in April 2014.

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