

# RELAXINE

## Film Coated Tablets

Active ingredient in each coated tablet:

Valerian dry extract 500 mg

For the inactive ingredients in the preparation - see section 6 "Further Information".

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

**The medicine is not intended for children under 12 years of age.** Take the medicine in the correct manner. Consult a pharmacist if you need further information.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for sedation in states of tension, nervousness and insomnia.

**Therapeutic group:** Sedative, herbal-based.

### 2. BEFORE USING THE MEDICINE

#### **⊗ Do not use the medicine:**

- If you are sensitive (allergic) to the active ingredient (valerian) or to any of the other ingredients contained in the medicine.
- If you are suffering from fructose intolerance, malabsorption of glucose-galactose or from a deficiency of the sucrase-isomaltase enzyme.
- In children under 12 years of age.

#### **Special warnings regarding use of this medicine**

- Do not use this medicine often or for a prolonged period without consulting a doctor.
- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- **Before treatment with Relaxine, tell the doctor if you are suffering from insomnia for a very long time.**

**⊗ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** In particular, inform the doctor or pharmacist if you are taking: additional hypnotics, anti-anxiety medicines, narcotic analgesics, additional sedatives.

#### **⊗ Use of the medicine and food**

Take the medicine with or before a meal.

#### **⊗ Use of the medicine and alcohol consumption**

Do not drink wines or alcoholic beverages during the course of treatment with the medicine.

#### **⊗ Pregnancy and breastfeeding**

If you are pregnant, are planning to become pregnant or are breastfeeding, consult a doctor or pharmacist before using the medicine, since there is not enough information regarding the safety of this preparation in these situations.

#### **⊗ Driving and operating machinery**

Relaxine may affect your ability to drive or to operate machinery and may cause sleepiness during the day. If this happens to you, do not drive or operate machinery.

#### **⊗ Important information regarding some of the ingredients of the medicine**

The preparation contains glucose and lactose. If you were told by the doctor that you are sensitive to certain sugars, consult the doctor before taking the medicine.

### 3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain as to how to use.

The usual dosage is:

**For adults and children over 12 years of age:** 1 or 2 tablets about half an hour before bedtime. Maximum 2 tablets per day.

**Do not exceed the recommended dose.**

**This medicine is not intended for children under 12 years of age.**

Do not crush/halve/chew it, since the tablet is coated. Swallow the medicine with water.

**Tests and follow-up:** When using for a prolonged period, follow-up and periodic tests by the doctor are necessary.

**If you accidentally took a higher dosage,** or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

### 4. SIDE EFFECTS

As with any medicine, use of Relaxine may cause side effects in some users.

If you suffer from a side effect, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

### 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from a doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package/blister. The expiry date refers to the last day of that month.
- Store in a dry place, protected from light, below 25°C.

### 6. FURTHER INFORMATION

• In addition to the active ingredient, the medicine also contains: Microcrystalline cellulose, hypromellose, talc, lactose, glucose, titanium dioxide, glycerol, magnesium stearate, colloidal silicone dioxide.

Each tablet contains 75 mg glucose and 150 mg lactose.

• **What does the medicine look like and what are the contents of the package:**

Each package contains 15 or 30 white, film coated tablets.

• **License holder and address:** Trima, Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000 Israel.

• **Manufacturer:** Laboratoires Pharmaceutiques Trenker SA, 32, Avenue Thomas Edison, 1402 Thines, Belgium

• Revised in April 2021 according to MOH guidelines.

• Registration number of the medicine in the National Drug Registry of the Ministry of Health: 115.58.29788.00