

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only  
**Name, form and strength of the preparation**

**Relert 20 mg**  
**Relert 40 mg**  
**Relert 80 mg**



**Film-coated Tablets**

Each film-coated tablet contains: **Eletriptan (as hydrobromide) 20 mg, 40 mg, 80 mg**

For the list of inactive ingredients in the preparation, see section 6.

**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.

This medicine has been prescribed to treat 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. This medicine is not usually intended for infants and children below the age of 18 and for adults over the age of 65. For information on side effects, please see section 4.

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

• For acute treatment at the headache stage of a migraine attack, with or without an aura (which can be manifested by vision problems, dulled senses and speech disturbances).

**Therapeutic group:**

Selective agonist of the vascular (5HT<sub>1B</sub>) and neuronal (5HT<sub>1D</sub>) serotonin receptors.

**2. BEFORE USING THE MEDICINE**

**Do not use the medicine if:**

- x you are sensitive (allergic) to the active ingredient or to any of the other ingredients that the medicine contains.
- x you are suffering, or have suffered in the past, from severely impaired function of the heart and/or blood vessels.
- x you are suffering, or have suffered in the past, from severely impaired function of the liver or kidney.
- x you are suffering, or have suffered in the past, from severe or untreated high blood pressure.
- x you are suffering, or have suffered in the past, from a stroke.
- x you are being concomitantly treated with the following medicines: ketoconazole, itraconazole (for treating fungal infection), erythromycin, clarithromycin, josamycin (antibiotics), ritonavir, indinavir, nelfinavir (for treating AIDS), and other 5HT<sub>1</sub> serotonin receptor agonists (for treating migraine).
- x Do not take medicines from the ergot group (for treating migraine) 24 hours before or after taking Relert.
- x you are suffering from a rare hereditary problem of intolerance to galactose, Lapp lactase deficiency or impaired absorption of glucose or galactose.

**Special warnings regarding use of the medicine:**

Do not use the medicine without consulting a doctor before commencing the treatment:

- if you are suffering, or have suffered in the past, from diabetes.
- If you smoke or are being treated with nicotine substitutes.
- If you are suffering, or have suffered in the past, from impaired function of the kidney/urinary tract.
- If you are male and over the age of 40.
- If you are female and post-menopausal.
- If you are suffering or if you know of a family history of coronary artery disease.
- If you are at increased risk of heart disease.
- If you are suffering, or have suffered in the past, from high blood pressure.
- If you are suffering from daily long-term headaches, associated with treatment for migraines.
- ! If you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- ! If you are sensitive to lactose. The preparation contains lactose and may cause allergy among people sensitive to lactose.
- ! The preparation contains the ingredient sunset yellow which may cause allergic reactions.

**! If you are taking, or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** It is especially important to inform the doctor or pharmacist if you are taking:

- The plant St. John's wort and medicines with serotonergic activity (such as medicines from the SSRI and/or SNRI groups) for treating depression - the combination may increase the risk of developing serotonin syndrome.
- Do not take this medicine if you are being concomitantly treated with ketoconazole, itraconazole (for treating fungal infection), erythromycin, clarithromycin, josamycin (antibiotics), ritonavir, indinavir, nelfinavir (for treating AIDS), and other 5HT<sub>1</sub> serotonin receptor agonists (for treating migraine).
- Do not take medicines from the ergot group (for treating migraine) 24 hours before or after taking Relert.

**! Use of the medicine and food**

The medicine can be taken with or without food. Swallow the tablet with a glass of water.

**! Pregnancy and breastfeeding**

Do not use the medicine without consulting a doctor before commencing the treatment if you are pregnant or breastfeeding, or planning to become pregnant or breastfeed. It is recommended to avoid breastfeeding for 24 hours after taking the medicine.

**! Driving and use of machinery**

Use of this medicine may impair alertness and therefore requires that caution be exercised when driving a car, operating dangerous machinery and when engaging in any activity which requires alertness.

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

Always use according to the doctor's instructions! The dosage and treatment regimen will be determined by the doctor only.

This medicine is not usually intended for infants and children below the age of 18 and for adults over the age of 65.

The medicine can be taken at any stage after appearance of the migraine headache, but it is best to do so as soon as possible. Do not take the medicine as a preventative treatment for migraine attacks.

Complete the treatment recommended by the doctor.

Even if there is an improvement in your health, do not discontinue treatment with the medicine without consulting with the doctor.

**Do not exceed the recommended dose!**

Do not crush/halve/chew the tablet, since it is film-coated.

**If you took an overdose or if a child accidentally swallowed the medicine, immediately proceed to a hospital emergency room and bring the package of the medicine with you.**

Adhere to the treatment regimen recommended by the doctor.

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

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

**4. SIDE EFFECTS**

As with any medicine, use of the medicine may cause side effects in some users. Do not be alarmed when reading the list of side effects, you may not suffer from any of them.

**Discontinue use and refer to a doctor immediately in the event of:**

An allergic reaction: breathing difficulties, wheezing, swelling in the region of the eyelids, face, and lips, widespread rash and itching (over the whole body).

Rapid heart rate, restlessness, hallucinations, loss of coordination, increased body temperature, sharp changes in blood pressure and overactive reflexes - symptoms of serotonin syndrome.

Severe pain or tightness in the chest or throat - symptoms of problems of the blood circulation of the heart (ischemic heart disease).

**Additional side effects which occur frequently** (frequency of up to 1:100):

Chest pain or tightness, palpitations, rapid heart rate, somnolence, headache, dizziness, spinning sensation (vertigo), reduced sensation of touch or pain, numbness, sore throat, dry mouth, abdominal pain, abdominal discomfort (dyspepsia), nausea, increased muscle tone (stiffness), muscle weakness, back pain, muscle pain, weakness, sensation of fever or flushing, chills, sweating, pharyngitis, runny nose.

**Additional side effects which occur infrequently** (at a frequency between 1:100 and 1:1,000):

Difficulty breathing, yawning, swelling of the face or hands and legs, inflammation or infection of the tongue, skin rash, itching, increased sensitivity to touch or pain, loss of coordination, difficult or slowed movement, tremor, speech disturbance, depersonalization, depression, abnormal thoughts, agitation, confusion, mood swings (euphoria), unresponsiveness, feeling ill, insomnia, loss of appetite and weight loss (anorexia), disturbed sense of taste, thirst, joint pain, degenerating joints, bone pain, increased volume and frequency of urination, impaired urinary system function, diarrhea, blurred vision, eye pain, intolerance to light, dry or watery eyes, pain or ringing in the ears, poor circulation.

**Additional side effects which occur rarely** (at a frequency between 1:1,000 and 1:10,000):

Shock, asthma, hives, skin disorders, swollen tongue, respiratory tract infection, swollen lymph glands, slow heart rate, emotional instability (mood swings), osteoarthritis, spasms, myopathy (muscle disease), constipation, inflamed gullet, belching, breast pain, heavy menstrual bleeding, conjunctivitis, voice change, increased blood bilirubin levels and changes in liver enzymes in blood tests.

**Additional side effects at an unknown frequency:**

Vomiting, increased blood pressure, fainting, ischemic colitis, myocardial ischemia, myocardial infarction, coronary artery spasm.

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

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

Store the medicine below 30°C.

Avoid poisoning! This medicine and any other medicine must be kept 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 the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

**6. FURTHER INFORMATION**

In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate, titanium dioxide (E171), hypromellose, glycerol triacetate and sunset yellow aluminium lake (E110).

The medicine contains lactose monohydrate:

Relert 20 mg: 23 mg.

Relert 40 mg: 46 mg.

Relert 80 mg: 92 mg.

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

Relert 20 mg: a round, orange tablet with "REP 20" imprinted on one side and "Pfizer" on the other side.

Relert 40 mg: a round, orange tablet with "REP 40" imprinted on one side and "Pfizer" on the other side.

Relert 80 mg: a round, orange tablet with "REP 80" imprinted on one side and "Pfizer" on the other side.

**Manufacturer:** R-PHARM Germany GmbH Heinrich-Mack-Str. 35, Illertissen 89257, Germany.

**License holder:** Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

This leaflet was checked and approved by the Ministry of Health in August 2013.

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

Relert 20 mg: 124.28.30370

Relert 40 mg: 124.29.30371

Relert 80 mg: 124.30.30372