



Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Relert[®] 20, 40, 80 mg, film-coated tablets

Each film-coated tablet contains eletriptan (as hydrobromide) 20, 40, 80 mg, respectively.

Inactive ingredients and allergens in the medicine – see section 6 “Additional information” and in section 2 “Important information about some of the ingredients of the medicine”.

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask 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 that their medical condition is similar to yours.

1. What is the medicine intended for?

For acute treatment of the headache phase of a migraine attack, with or without aura (which can be manifested in vision problems, numbness and speech disorders).

Therapeutic group: selective serotonin receptor agonist.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (eletriptan), or to any of the other ingredients this medicine contains (see section 6).
- You have severe liver or kidney disease.
- You have moderate to severe high blood pressure or untreated mild high blood pressure.
- You have ever had heart problems (e.g., heart attack, angina pectoris, heart failure or significant abnormal heart rhythm (arrhythmia), temporary, sudden narrowing of one of the coronary arteries).
- You have a disorder of blood circulation (peripheral vascular disease).
- You have ever had a stroke (even a mild one that lasted for only a few minutes or hours).
- You have taken ergotamine or medicines like ergotamine (including methysergide) within 24 hours before or after taking **Relert**.
- You are taking other medicines whose names end in “triptan” (e.g., sumatriptan, rizatriptan, naratriptan, zolmitriptan, almotriptan and frovatriptan).

Special warnings regarding the use of the medicine

Before the treatment with Relert, tell the doctor if:

- You suffer from diabetes.
- You smoke or are being treated with nicotine replacement therapy.
- You are a man over 40 years old.
- You are a post-menopausal woman.
- You or anybody in your family has coronary artery disease.
- You have been told in the past that you may have a high risk of heart disease, consult the doctor before using **Relert**.

Frequent use of migraine medicines

If you repeatedly use **Relert** or other medicines for the treatment of migraines over several days or weeks, this can cause daily long-term headaches. Tell the doctor if you suffer from this, as you might need to stop treatment for a while.

Children and adolescents

This medicine is not intended for children and adolescents under the age of 18.

Elderly

This medicine is not intended for patients over the age of 65.

Tests and follow-up

During the period of treatment with the medicine, you may be referred by the doctor for blood tests to check for elevated liver enzymes or other blood problems.

Drug interactions

If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Taking Relert with certain medicines may cause serious side effects. Do not take Relert if:

- You have taken ergotamine or medicines like ergotamine (including methysergide) within 24 hours before or after taking **Relert**.
- You are taking other medicines whose names end in “triptan” (e.g., sumatriptan, rizatriptan, naratriptan, zolmitriptan, almotriptan and frovatriptan).

Certain medicines can affect the way **Relert** works, or **Relert** itself can decrease the effectiveness of other medicines taken at the same time. These include:

- Medicines for treatment of fungal infections (e.g., ketoconazole and itraconazole).
- Medicines for treatment of bacterial infections (e.g., erythromycin, clarithromycin and josamycin).
- Medicines for treatment of AIDS and HIV (e.g., ritonavir, indinavir and nelfinavir).

Do not take the herbal preparation St. John’s Wort (*Hypericum perforatum*) at the same time as **Relert**. If you have already started taking St. John’s Wort, consult the doctor before you stop using it.

Tell the doctor before starting treatment with **Relert** if you are taking certain medicines (selective serotonin reuptake inhibitors [SSRIs] or serotonin-norepinephrine reuptake inhibitors [SNRIs]) for the treatment of depression and other mental disorders. The use of these medicines in combination with certain medicines for treatment of migraines may increase the risk of developing serotonin syndrome. For additional information about symptoms of serotonin syndrome see section 4 “Side effects”.

Use of the medicine and food

The medicine may be taken before or after a meal.

Pregnancy and breastfeeding

Consult with your doctor or pharmacist before taking any medicine.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor before using this medicine.

It is recommended to avoid breastfeeding for 24 hours after taking this medicine.

Driving and using machines

The use of **Relert** or the migraine itself may make you sleepy. This medicine can also make you feel dizzy. Therefore, avoid driving and using machines during a migraine attack or after taking the medicine.

Important information about some of the ingredients of the medicine

Relert contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Relert contains Sunset yellow FCF aluminium lake (E110), which may cause allergic reactions.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say, essentially “sodium-free”.

3. How to use the medicine?

Always use the medicine according to the doctor’s instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

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

The medicine can be taken at any stage after the start of the migraine headache, but it is best to take it as soon as possible. **However, you should only take the medicine during the headache phase of the migraine attack.**

Do not take the medicine to prevent a migraine attack.

- The usual starting dosage is 40 mg.
- If the migraine is not relieved after taking the first tablet, do not take another tablet for the same migraine attack.
- If the migraine is relieved after taking the first tablet, and then worsens again, you can take another tablet. However, you should wait at least two hours before taking the second tablet.
- Do not take a dosage higher than 160 mg within 24 hours.
- If one 40 mg tablet does not relieve the migraine, consult the doctor, who may decide to increase the dosage for future attacks.

Do not exceed the recommended dose.

Patients with impaired kidney function

The medicine can be used in patients with mild or moderate kidney function impairment. In these patients, the recommended starting dosage is 20 mg, and the maximum daily dosage is 40 mg. The dosage adjustment will be done by the doctor.

Patients with impaired liver function

The medicine can be used in patients with mild or moderate liver function impairment, and no dosage adjustment is required.

Method of administration

The medicine should be swallowed whole with water. Do not crush/halve/chew the tablet, since it is film-coated.

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 doctor or a hospital emergency room and bring the package of the medicine with you. Side effects due to taking an overdose include high blood pressure and heart problems.

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 on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Relert** 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.

Refer to the doctor immediately if you experience one or more of the following symptoms after taking the medicine:

- Sudden wheeziness, difficulty breathing, swelling of eyelids, face or lips, rash or itching (especially if they affect the whole body), as this may be a sign of a hypersensitivity reaction.
- Chest pain and tightness, which may be intense and involve the throat. These may be symptoms of a disorder of blood flow to the heart (ischemic heart disease).
- Signs and symptoms of serotonin syndrome, which may include restlessness, hallucinations, loss of coordination, fast heartbeat, increased body temperature, fast changes in blood pressure and heightened reflexes.

Additional side effects

Common side effects (effects that occur in 1-10 out of 100 users):

- Chest pain or tightness or pressure, awareness of your heartbeats (palpitations), rapid heart rate
- Dizziness, sensation of spinning or whirling (vertigo), headache, feeling sleepy, reduced sense of touch or pain
- Sore throat, throat tightness, dry mouth
- Abdominal and stomach pain, indigestion (upset stomach), nausea (sensation of discomfort in stomach or abdomen with an urge to vomit)
- Stiffness (increased muscle tone), muscle weakness, back pain, muscle pain
- Generally feeling weak, feeling hot, chills, runny nose, sweating, tingling or abnormal sensation, flushing, pain

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):

- Difficulty breathing, yawning
- Swelling of the face or hands and feet, inflammation or infection of the tongue, skin rash, itching
- Increased sense of touch or pain, loss of coordination, slow movement or difficulty in movement, tremor, speech impairment
- Feeling detached from yourself, depression, thinking strangely, feeling agitated, feeling confused, elated mood (euphoria), states of unresponsiveness (stupor), general feeling of discomfort, feeling unwell, sleeplessness (insomnia)
- Loss of appetite and weight loss (anorexia), taste disturbance, thirst
- Degeneration of the joints (arthrosis), bone pain, joint pain
- Increased need to pass urine, urinating disorders, passing excessive quantity of urine, diarrhea
- Abnormal vision, eye pain, intolerance to light, dry or watery eyes
- Ear pain, ringing in the ears (tinnitus)
- Disorder of blood circulation (peripheral vascular disease)

Rare side effects (effects that occur in 1-10 out of 10,000 users):

- Shock, asthma, hives (urticaria), skin disorders, swollen tongue
- Respiratory tract infection, swollen lymph glands
- Slow heart rate
- Emotionally fragile (mood swings)
- Degeneration of joints (arthritis, joint inflammation), muscle disorders, twitching
- Constipation, inflamed gullet, belching
- Chest pain, increased or prolonged menstrual bleeding
- Eye infection (conjunctivitis)
- Changes to voice

Additional side effects that have been reported include fainting, high blood pressure, inflammation of the large intestine, vomiting, stroke, inadequate heart blood flow, heart attack, heart muscle/coronary artery spasm.

You may be referred by the doctor for blood tests to check for elevated liver enzymes or other blood problems.

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 the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via 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 closed place out of the reach and sight 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 (Expiry date) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store below 30°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

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

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

What the medicine looks like and what the package contains:

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

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

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

Approved package sizes: 2, 3, 4, 5, 6 or 10 tablets. Not all package sizes may be marketed.

Revised in March 2025 according to MOH guidelines.

Drug registration number at 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

Manufacturer and registration holder: Dexcel Pharma Technologies Ltd., 10 Hakidma St., Yokneam Illit, 2069200, Israel