Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

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

List of inactive ingredients and allergens: See section 2 under **'Important information about some of this medicine's ingredients'** and section 6 **'Further information'**.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult 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 THIS MEDICINE INTENDED FOR?

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

Therapeutic group:
Selective serotonin receptor agonist.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (listed in 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, heart failure or significant abnormal heart rhythm (arrhythmia), temporary and sudden narrowing of one of the coronary arteries).
- You have poor blood circulation (peripheral vascular disease).
- You have ever had a stroke (even a mild one that lasted for only a few minutes or hours).
- If you have taken ergotamine or medicines like ergotamine (including methysergide) within 24 hours before or after taking Relert®.
- You are taking any other medicines that end in 'triptan' (for example, sumatriptan, rizatriptan, naratriptan, zolmitriptan, almotriptan and frovatriptan).

Special warnings regarding use of the medicine
Before treatment with Relert®, tell your doctor if:
- You have diabetes.
- You smoke or use nicotine replacement therapy.
- You are a man over the age of 40.
- You are a post-menopausal woman.
- You or anybody in your family have coronary artery disease.
- You have ever been told that you may have an increased risk of heart disease, consult your doctor before using Relert®.

Repeat use of migraine medicines
If you repeatedly use Relert® or any medicines for the treatment of migraines over several days or weeks, this can cause daily long-term headaches. Tell your doctor if you experience this, as you might need to stop treatment for a while.

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

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

Patients with kidney impairment
This medicine can be used in patients with mild or moderate kidney impairment. In these patients, a starting dose of 20 mg is recommended, and the maximum daily dose is 40 mg. Your doctor will adjust the dose.

Patients with liver impairment
This medicine can be used in patients with mild or moderate liver impairment and no dose adjustment is required.

Tests and follow-up
During treatment, your doctor may refer you for a blood test to check for elevated liver enzymes and other blood problems.

Drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist.

Taking Relert® together with some 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 any other medicines that end in 'triptan' (for example, sumatriptan, rizatriptan, naratriptan, zolmitriptan, almotriptan and frovatriptan).

Some medicines can affect the way Relert® works or Relert® itself can reduce the effectiveness of other medicines taken at the same time. These include:
- Drugs used to treat fungal infections (e.g., ketoconazole and itraconazole).
- Drugs used to treat bacterial infections (e.g., erythromycin, clarithromycin and josamycin).
- Drugs used to treat AIDS and HIV (e.g., ritonavir, indinavir and nelfinavir).

The herbal preparation St. John's wort (*Hypericum perforatum*) should not be taken at the same time as Relert®. If you already started taking St. John's wort preparation, consult your doctor before you stop taking it.

Tell your doctor before you start treatment with Relert® if you are taking medicines in the SSRI* or SNRI** family for depression and other mental disorders. These medicines may increase the risk of developing serotonin syndrome during combined use with certain migraine medications. See Section 4, Side effects for more information on the symptoms of serotonin syndrome.
SSRI* - Selective serotonin re-uptake inhibitors.
SNRI** - Serotonin norepinephrine re-uptake inhibitors.

Using this medicine and food
The medicine can be taken before or after food.

Pregnancy and breastfeeding
Do not use this medicine without consulting your doctor before starting treatment if you are pregnant or breastfeeding, think you might be pregnant or are planning to become pregnant.
It is recommended to avoid breastfeeding for 24 hours after taking this medicine.

Driving and using machines
Use of Relert® or the migraine itself may make you sleepy. This medicine may also make you feel dizzy. Therefore, avoid driving and using machines during the migraine attack or after taking your medicine.

Important information about some of this medicine's ingredients
Relert® contains lactose, Sunset Yellow Aluminium Lake (E 110) and sodium
Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

The dye Sunset Yellow may cause allergic reactions.
Relert® tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO USE THIS MEDICINE?

Always use this preparation according to your doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by your doctor only.
The medicine can be taken at any time 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. You should not take this medicine to prevent a migraine attack.**
- The usual starting dose is 40 mg.
- If the first tablet does not relieve your migraine, do not take a second tablet for the same migraine attack.
- If after a first tablet your migraine is relieved and then comes back, you may take a second tablet. However, you must wait at least 2 hours before taking the second tablet.
- You should not take a dose that is higher than 160 mg within 24 hours.
- If one 40 mg tablet does not relieve your migraine, consult your doctor, who may decide to increase the dose for future attacks.

Do not exceed the recommended dose.
Swallow the medicine whole with water.
Do not crush/split/chew the tablet, as it is coated.
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Relert® may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Contact your doctor immediately if you experience any of the following symptoms after taking this medicine:
- Sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting 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 problems of the blood circulation of the heart (ischaemic heart disease).
- Signs and symptoms of serotonin syndrome which may include restlessness, hallucinations, loss of co-ordination, fast heartbeat, increase body temperature, fast changes in blood pressure and overactive reflexes.

Additional side effects
Common side effects (may affect up to 1 in 10 people): Chest pain or tightness or pressure, heart palpitations, increased heart rate, dizziness, sensation of spinning or whirling (vertigo), headache, feeling sleepy, reduced sense of touch or pain, sore throat, throat tightness, dry mouth, stomach pain, indigestion (upset stomach), nausea (sensation of unease and discomfort in stomach 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 (may affect up to 1 in 100 people): 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 co-ordination, slow or reduced movement, tremor, slurred speech, not feeling one self (depersonalisation), depression, thinking strangely, feeling agitated, feeling confused, mood swings (euphoria), periods of unresponsiveness (stupor), general feeling of discomfort, malaise, sleeplessness, loss of appetite and weight loss (anorexia), taste disturbance, thirst, degeneration of the joints (arthrosis), bone pain, joint pain, increased need to urinate, problems with urinating, passing excessive quantity of urine, diarrhoea, abnormal vision, eye pain, intolerance to light, dry or watery eyes, ear pain, ringing in the ears (tinnitus), poor circulation (peripheral vascular disorder).

Rare side effects (may affect up to 1 in 1,000 people): Shock, asthma, hives (urticaria), skin disorder, swollen tongue, throat or chest infection, swollen lymph glands, slow heart rate, emotionally fragile (mood swings), degeneration of joints (arthritis), muscle disorder, twitching, constipation, inflamed gullet, belching, breast pain, heavy or prolonged menstrual periods, eye infection (conjunctivitis), changes to voice.

Other side effects reported
Fainting, high blood pressure, inflammation of the large intestine, vomiting, brain and blood vessel-related accident, inadequate heart blood flow, heart attack, heart muscle/artery-related spasm.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link "Reporting Side Effects of Drug Treatment" on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects, or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept 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 a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store the medicine below 30°C.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:
microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate, titanium dioxide (E171), hypromellose, glycerol triacetate and sunset yellow FCF aluminium lake (E110).

The medicine contains lactose monohydrate:
Relert® 20 mg: 23 mg.
Relert® 40 mg: 46 mg.
Relert® 80 mg: 92 mg.

What the medicine looks like and contents of the pack:
Relert® 20 mg: A round, orange tablet marked "REP 20" on one side and "Pfizer" on the other side.
Relert® 40 mg: A round, orange tablet marked "REP 40" on one side and "Pfizer" on the other side.
Relert® 80 mg: A round, orange tablet marked "REP 80" on one side and "Pfizer" on the other side.

The medicine is marketed in a package that contains 2, 3, 4, 5, 6 or 10 tablets.

Not all pack sizes may be marketed.

Registration holder and address:
Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
Relert® 20 mg: 124.28.30370
Relert® 40 mg: 124.29.30371
Relert® 80 mg: 124.30.30372

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