PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:

RELPAX® 20 mg Tablets

RELPAX® 40 mg Tablets

RELPAX® 80 mg Tablets

Eletriptan hydrobromide

Read all of this leaflet carefully before you start taking RELPAX:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask you doctor or your pharmacist.
- RELPAX has been prescribed for you personally and you should not share your medicines with other people. It may harm them, even if their symptoms are the same as yours.

WHAT RELPAX CONTAINS:

The active ingredient in RELPAX is eletriptan.

Each RELPAX tablet contains 20, 40 or 80 mg eletriptan as eletriptan hydrobromide respectively.

The other ingredients are: Croscarmellose sodium, glycerol triacetate, hypromellose, lactose, magnesium stearate, microcrystalline cellulose and the colourants sunset yellow aluminium lake and titanium dioxide.

This medicine contains sugar.

RELPAX 20 mg tablets contain 23 mg lactose per tablet.

RELPAX 40 mg tablets contain 46 mg lactose per tablet.

RELPAX 80 mg tablets contain 92 mg lactose per tablet.

WHAT RELPAX IS USED FOR:

RELPAX is used to treat migraine headache in individuals and children 18 years and older. Before the start of a migraine headache, you may experience a phase called an aura, which can involve vision disorders, numbness and speech disorders.

Do not take RELPAX to prevent an attack of migraine.

BEFORE YOU TAKE RELPAX:

Do not take RELPAX:

- If you are hypersensitive (allergic) to eletriptan or any of the other ingredients of RELPAX.
- If you have severe liver disease.
- If you have high blood pressure which is not well controlled.
- If you have ever had heart problems, such as a heart attack or angina.
- If you have poor circulation (peripheral vascular disease).
- If you have a condition that stops blood flowing through your arteries.
- If you have ever had a stroke (even a mild one that lasted for only a few minutes or hours).
- If you have taken ergotamine (a class of medicines used to treat migraine headaches) or medicines based on ergot within 24 hours before or after taking RELPAX.
- If you have taken medicines used to treat depression or other mental illness
- If you are being treated with certain antibiotics (e.g. medicines like erythromycin, clarithromycin used to treat bacterial infections), antifungals (e.g. medicines like ketoconazole, itraconazole used to treat fungal infections) or using medicines to treat Acquired Immune Deficiency Syndrome (AIDS) or Human Immunodeficiency Virus (HIV) (e.g. ritonavir, indinavir and nelfinavir) inform your doctor as taking RELPAX with such medicines may affect the way it works.
- If you are less than 18 years of age.

Take special care with RELPAX:

- If you are taking other medicines to control your mood, appetite or sleep, talk to your doctor as this may have additional side effects.
- If you have ever been told that you may have an increased risk of heart disease, you should discuss this with your doctor before using RELPAX.

- If you repeatedly use RELPAX or any medications for the treatment of migraine over several days or weeks, this can cause daily long-term headaches. Tell your doctor if you experience this.
- If you are diabetic as RELPAX contains lactose (a type of sugar).
- If you take 60 mg or more of RELPAX, you might experience slight and short term increases in blood pressure, especially if you have a kidney disease or are over 65 years of age.

Taking RELPAX with food and drink:

RELPAX tablets should be swallowed whole with water before or after food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking this medicine.

The safety of RELPAX in pregnant women has not been established.

RELPAX is excreted in breastmilk. It is recommended to avoid breastfeeding after taking this medicine.

Driving and using machinery:

RELPAX tablets may make you drowsy. RELPAX tablets may also make you feel dizzy, therefore you should not drive or use machinery during the migraine attack or after taking RELPAX.

Important information about some of the ingredients of RELPAX:

RELPAX contains lactose. Patients with rare hereditary conditions of lactose or galactose intolerance e.g. galactosaemia should not take RELPAX. It may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with RELPAX:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- Certain antibiotics (e.g. medicines like erythromycin, clarithromycin used to treat bacterial infections), antifungals (e.g. medicines like ketoconazole, itraconazole used to treat fungal infections) or using medicines to treat AIDS or HIV (e.g. ritonavir, indinavir and nelfinavir) inform your doctor as taking RELPAX may interfere with such medicines may affect the way it works.

- Ergotamine or medicines derived from ergotamine (a medicine used to treat migraine) should not be taken within 24 hours before or after taking RELPAX as it may increase your blood pressure.
- Antidepressants (serotonin norepinephrine re-uptake inhibitor (SNRIs) or selective serotonin re-uptake inhibitor (SSRIs) like pethidine, tramadol or St. John's Wort (*Hypericum perforatum*) may cause side effects. Inform your doctor as taking RELPAX along with these medicines may cause side effects. Your doctor will need to monitor your response when RELPAX treatment starts.

HOW TO TAKE RELPAX:

Do not share medicines prescribed for you with any other person.

Always take RELPAX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

RELPAX should be taken as early as possible after the start and only during the headache phase of the migraine. You should not take RELPAX during the aura phase or to prevent a migraine attack.

Adults (18 – 65 years of age):

The recommended initial dose is 40 mg. The tablets should be swallowed whole with a drink of water. If the first tablet does not relieve your migraine, you should not take a second tablet for the same attack. If after the 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.

If you find that a dose of one 40 mg tablet does not relieve your migraines, tell your doctor as he or she may decide to increase the dose to 80 mg for future attacks. The maximum total daily dose should not exceed 160 mg.

Elderly (over 65 years of age):

Safety and efficacy of RELPAX tablets have not been assessed for patients over 65 years of age.

Patients with liver problems:

RELPAX can be used in patients with mild or moderate liver problems. No dose adjustment is needed. RELPAX is contraindicated in patients with severe liver diseases.

Patients with kidney problems:

RELPAX can be used in patients with mild or moderate kidney problems. The total daily dose should not be more than 40 mg. Your doctor will inform you on your dose.

Your doctor will tell you how long your treatment with RELPAX will last. Do not stop treatment early.

If you have the impression that the effect of RELPAX is too strong or too weak, tell your doctor or pharmacist.

If you take more RELPAX than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take a dose of RELPAX:

Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS:

RELPAX can have side effects.

Not all side effects for RELPAX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking RELPAX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions such as rash or itching as this may be a sign of hypersensitivity reaction.
- Chest pain or tightness.
- Skin reactions such as red sore skin and flaking (dermatitis), rash, itching, or swelling, particularly around the face and neck called angioedema.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to RELPAX. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Dizziness, headache, muscle stiffness, increased sense of touch or pain, muscle weakness, tingling or abnormal sensations, feeling tired or sleepy.
- Sensation of spinning or whirling (vertigo).
- Palpitations or increased heart rate.
- Sensation of warmth or flushing.

- Inflammation of the back of the throat (pharyngitis), throat tightness.
- Abdominal/stomach pain, dry mouth, indigestion, nausea.
- Sweating.
- Back pain and chills.
- Weakness, and chest pain or tightness, chills and pain.

Less frequent side effects:

- Fainting.
- High blood pressure.
- Vomiting, inflammation of the large intestine (colitis ischaemic).
- Heart conditions including heart attack and chest pain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Should your general health worsen while taking this medicine, please consult your healthcare provider for advice.

STORAGE AND DISPOSAL INFORMATION OF RELPAX:

Store all medicines out of reach of children.

Store in a cool dry place at or below 25 °C.

Keep container tightly closed.

Do not take RELPAX after the expiry date shown on the blister and carton. If your medicine is out of date, take it to your pharmacist who will dispose of it safely.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF RELPAX:

RELPAX tablets are supplied in blister packs containing either 2 or 4 tablets.

IDENTIFICATION AND DESCRIPTION OF RELPAX:

RELPAX tablets are orange, standard round convex film-coated tablets.

RELPAX 20 mg tablets are debossed with “REP 20” on one side and ”VLE” on the other.

RELPAX 40 mg tablets are debossed with “REP 40” on one side and ”VLE” on the other.

RELPAX 80 mg tablets are debossed with “REP 80” on one side and ”VLE” on the other.

REGISTRATION NUMBER:

RELPAX 20 mg tablets: 34/7.3/0077

RELPAX 40 mg tablets: 34/7.3/0078

RELPAX 80 mg tablets: 34/7.3/0079

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Viatris Healthcare (Pty) Ltd

4 Brewery Street

Isando

Gauteng, 1609

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Manufacturer: Pfizer Italia S.r.l., Ascoli Piceno, Italy

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

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BOTSWANA: S2

RELPAX 20 mg – Reg. No.: BOT1001622

RELPAX 40 mg – Reg. No.: BOT1001620

RELPAX 80 mg – Reg. No.: BOT1001621

NAMIBIA: NS2

RELPAX 20 mg – Reg. No.: 04/7.3/1241

RELPAX 40 mg – Reg. No.: 04/7.3/1242

RELPAX 80 mg – Reg. No.: 04/7.3/1243