PATIENT INFORMATION LEAFLET

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PATIENT INFORMATION LEAFLET (PIL) TEMPLATE

<text> signifies text to be selected or deleted as appropriate while {text} refers to information to be added.]

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

{(Invented) name strength pharmaceutical form}[1]:
PRELYNCA 50mg/75mg/150mg Capsules

{Active pharmaceutical ingredient(s)}
Pregabalin

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. WHAT PRELYNCA IS AND WHAT IT IS USED FOR

PRELYNCA contains the active ingredient Pregabalin. Pregabalin is an anti-epileptic drug, also called an anticonvulsant. It works by slowing down impulses in the brain that cause seizures. Pregabalin also affects chemicals in the brain that send pain signals across the nervous system.

PRELYNCA is a prescription medicine used in adults, 18 years and older, to treat:

- pain from damaged nerves (neuropathic pain) that happens with diabetes
- pain from damaged nerves (neuropathic pain) that follows healing of shingles
- partial seizures when taken together with other seizure medicines
- fibromyalgia (pain all over your body)
- pain from damaged nerves (neuropathic pain) that follows spinal cord injury

PRELYNCA has not been studied in children under 18 years of age.

2. BEFORE YOU TAKE PRELYNCA

Do not take PRELYNCA

If you are allergic to pregabalin or any of the other ingredients of this medicine.

Take special care with PRELYNCA

Talk to your doctor or pharmacist before taking PRELYNCA.

- Some patients taking PRELYNCA have reported symptoms suggesting an allergic reaction. These symptoms include swelling of the face, lips, tongue, and throat, as well as diffuse skin rash. Should you experience any of these reactions, you should contact your physician immediately.
- PRELYNCA has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in elderly patients. Therefore, you should be careful until you are used to any effect the medicine might have.
- PRELYNCA may cause blurring or loss of vision, or other changes in eyesight, many of which are temporary. You should immediately tell your doctor if you experience any changes in your vision.
- Some patients with diabetes who gain weight while taking pregabalin may need an alteration in their diabetic medicines.
- Certain side effects may be more common, such as sleepiness, because patients with spinal cord injury may be taking other medicines to treat, for example, pain or spasticity, that have similar side effects to Pregabalin and the severity of these effects may be increased when taken together.
- There have been reports of heart failure in some patients when taking PRELYNCA; these patients were mostly elderly with cardiovascular conditions. Before taking this medicine you should tell your doctor if you have a history of heart disease.
- There have been reports of kidney failure in some patients when taking PRELYNCA. If while taking PRELYNCA you notice decreased urination, you should tell your doctor as stopping the medicine may improve this.
- A small number of people being treated with anti-epileptics such as PRELYNCA have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- When PRELYNCA is taken with other medicines that may cause constipation (such as some types of pain medicines) it is possible that gastrointestinal problems may occur (e.g. constipation, blocked or paralysed bowel). Tell your doctor if you experience constipation, especially if you are prone to this problem.
- Before taking this medicine you should tell your doctor if you have a history of alcoholism or any drug abuse or dependence. Do not take more medicine than prescribed.
- There have been reports of convulsions when taking PRELYNCA or shortly after stopping PRELYNCA. If you experience a convulsion, contact your doctor immediately.
- There have been reports of reduction in brain function (encephalopathy) in some patients taking PRELYNCA when they have other conditions. Tell your doctor if you have a history of any serious medical conditions, including liver or kidney disease.

Children and adolescents
The safety and efficacy in children and adolescents (under 18 years of age) has not been established and therefore, PRELYNCA should not be used in this age group.

Taking with other medicines
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

PRELYNCA and certain other medicines may influence each other (interaction). When taken with certain other medicines, PRELYNCA may potentiate the side effects seen with these medicines, including respiratory failure and coma. The degree of dizziness, sleepiness and decreased concentration may be increased if PRELYNCA is taken together with medicines containing:

Oxycodone – (used as a pain-killer)
Lorazepam – (used for treating anxiety)
Alcohol

PRELYNCA may be taken with oral contraceptives.

Taking PRELYNCA with food and drink

PRELYNCA capsules may be taken with or without food.
It is advised not to drink alcohol while taking PRELYNCA.

Pregnancy and breast-feeding
PRELYNCA should not be taken during pregnancy or when breast-feeding, unless you are told otherwise by your doctor. Effective contraception must be used by women of child-bearing potential. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
PRELYNCA may produce dizziness, sleepiness and decreased concentration. You should not drive, operate complex machinery or engage in other potentially hazardous activities until you know whether this medicine affects your ability to perform these activities.

3. HOW TO TAKE PRELYNCA

Always take this medicine exactly as your doctor has told you.
Check with your doctor or pharmacist if you are not sure.
Your doctor will determine what dose is appropriate for you. PRELYNCA is for oral use only.

- Take the number of capsules as instructed by your doctor.
- The dose, which has been adjusted for you and your condition, will generally be between 150 mg and 600 mg each day.
- Your doctor will tell you to take PRELYNCA either twice or three times a day. For twice a day take PRELYNCA once in the morning and once in the evening, at about the same time each day. For three times a day take PRELYNCA once in the morning, once in the afternoon and once in the evening, at about the same time each day.

If you have the impression that the effect of PRELYNCA is too strong or too weak, talk to your doctor or pharmacist.

If you are an elderly patient (over 65 years of age), you should take PRELYNCA normally except if you have problems with your kidneys.

Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

Swallow the capsule whole with water.

Continue taking PRELYNCA until your doctor tells you to stop

If you take more PRELYNCA than you should
Call your doctor or go to the nearest hospital emergency unit immediately. Take your box or bottle of PRELYNCA capsules with you. You may feel sleepy, confused, agitated, or restless as a result of taking more PRELYNCA than you should. Fits have also been reported.

If you forget to take PRELYNCA
It is important to take your PRELYNCA capsules regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten dose.

If you stop taking PRELYNCA
Do not stop taking PRELYNCA unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of 1 week.

After stopping long and short-term PRELYNCA treatment, you need to know that you may experience certain side effects. These include, trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flulike symptoms, convulsions, nervousness, depression, pain, sweating, and dizziness. These symptoms may occur more commonly or severely if you have been taking PRELYNCA for a longer period of time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common: may affect more than 1 in 10 people
Dizziness, drowsiness, headache.

Common: may affect up to 1 in 10 people
- Increased appetite.
- Feeling of elation, confusion, disorientation, decrease in sexual interest, irritability.
- Disturbance in attention, clumsiness, memory impairment, loss of memory, tremor, difficulty with speaking, tingling feeling, numbness, sedation, lethargy, insomnia, fatigue, feeling abnormal.
- Blurred vision, double vision.
- Vertigo, problems with balance, fall.

- Dry mouth, constipation, vomiting, flatulence, diarrhoea, nausea, swollen abdomen.
- Difficulties with erection.
- Swelling of the body including extremities.
- Feeling drunk, abnormal style of walking.
- Weight gain.
- Muscle cramp, joint pain, back pain, pain in limb.
- Sore throat.

Uncommon: may affect up to 1 in 100 people

- Loss of appetite, weight loss, low blood sugar, high blood sugar.
- Change in perception of self, restlessness, depression, agitation, mood swings, difficulty finding words, hallucinations, abnormal dreams, panic attack, apathy, aggression, elevated mood, mental impairment, difficulty with thinking, increase in sexual interest, problems with sexual functioning including inability to achieve a sexual climax, delayed ejaculation.
- Changes in eyesight, unusual eye movement, changes in vision including tunnel vision, flashes of light, jerky movements, reduced reflexes, increased activity, dizziness on standing, sensitive skin, loss of taste, burning sensation, tremor on movement, decreased consciousness, loss of consciousness, fainting, increased sensitivity to noise, feeling unwell.
- Dry eyes, eye swelling, eye pain, weak eyes, watery eyes, eye irritation.
- Heart rhythm disturbances, increased heart rate, low blood pressure, high blood pressure, changes in heartbeat, heart failure.
- Flushing, hot flushes.
- Difficulty breathing, dry nose, nasal congestion.
- Increased saliva production, heartburn, numb around mouth.
- Sweating, rash, chills, fever.
- Muscle twitching, joint swelling, muscle stiffness, pain including muscle pain, neck pain.
- Breast pain.
- Difficulty with or painful urination, incontinence.
- Weakness, thirst, chest tightness.
- Changes in blood and liver test results (blood creatinine phosphokinase increased, alanine amino transferase increased, aspartate aminotransferase increased, platelet count decreased, neutropaenia, increase in blood creatinine, decrease in blood potassium).
- Hypersensitivity, swollen face, itchiness, hives, runny nose, nose bleed, cough, snoring.
- Painful menstrual periods.
- Coldness of hands and feet.

Rare: may affect up to 1 in 1,000 people

- Abnormal sense of smell, swinging vision, altered perception of depth, visual brightness, vision loss.
- Dilated pupils, cross eyes.
- Cold sweat, tightness of the throat, swollen tongue.
- Inflammation of the pancreas.
- Difficulty in swallowing.
- Slow or reduced movement of the body.
- Difficulty with writing properly.
- Increased fluid in the abdomen.
- Fluid in the lungs.
- Convulsions.

- Changes in the recording of electrical changes (ECG) in the heart which correspond to heart rhythm disturbances.
- Muscle damage.
- Breast discharge, abnormal breast growth, breast growth in males.
- Interrupted menstrual periods.
- Kidney failure, reduced urine volume, urinary retention.
- Decrease in white blood cell count.
- Inappropriate behaviour.
- Allergic reactions (which may include difficulty breathing, inflammation of the eyes (keratitis) and a serious skin reaction characterized by rash, blisters, peeling skin and pain).
- Jaundice (yellowing of the skin and eyes).

Very rare: may affect up to 1 in 10,000 people
- Liver failure.
- Hepatitis (inflammation of the liver).

If you experience swollen face or tongue or if your skin turns red and starts to blister or peel, you should seek immediate medical advice.

Certain side effects may be more common, such as sleepiness, because patients with spinal cord injury may be taking other medicines to treat, for example, pain or spasticity, that have similar side effects to Pregabalin and the severity of these effects may be increased when taken together.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE PRELYNCA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or bottle.

The expiry date refers to the last day of that month.

Store at temperatures not exceeding 30 °C

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What PRELYNCA contains:

The active pharmaceutical ingredient is pregabalin. Each hard capsule contains either 50 mg, 75 mg, or 150 mg of pregabalin.

PRELYNCA 50 mg

Active: Pregabalin

Inactive: Pregelatinized Starch, Mannitol (spray dried), Talc & “Size 3” hard gelatin capsule with white cap and white body.

PRELYNCA 75 mg

Active: Pregabalin

Inactive: Pregelatinized Starch, Mannitol (spray dried), Talc & “Size 3” hard gelatin capsule with Swedish Orange cap and White body.

PRELYNCA 150 mg

Active: Pregabalin

Inactive: Pregelatinized Starch, Mannitol (spray dried), Talc & “Size 1” hard gelatin capsule with white cap and white body.

What PRELYNCA looks like and contents of the pack:

PRELYNCA 50 mg: White powder in a White cap and White body hard gelatin capsule, imprinted with ‘50’ on the body.

PRELYNCA 75 mg: White powder in a Swedish Orange cap and White body hard gelatin capsule, imprinted with ‘75’ on the body

PRELYNCA 150 mg: White powder in a White cap and White body hard gelatin capsule, imprinted with ‘150’ on the body.

PRELYNCA is available in following pack sizes made of PVC with an aluminium foil backing:

For 50 mg: 21 capsules: 3x7's capsules
7capsules packed in PVC/Aluminium foil blisters and 3 such blisters are packed in carton along with the pack insert.

For 75 mg: 28 capsules i.e 2x14 capsules
14 capsules packed per PVC/Aluminium foil blisters and 2 such blisters of 14 capsules are packed in carton along with the pack insert.

For 150 mg: 28 capsules i.e 2x14 capsules
14 capsules packed per PVC/Aluminium foil blisters and 2 such blisters of 14 capsules are packed in carton along with the pack insert.

Manufactured by: PHARMATHEN INTERNATIONAL S.A.
Industrial Park Sapes, Rodopi Prefecture, Block No 5,
Rodopi 69300, Greece

Manufactured for: MEGA LIFESCIENCES (AUSTRALIA) PTY LTD
Victoria 3810, Australia.

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