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

This medicine is dispensed with a doctor's prescription only

Pregabalin Taro 75 mg
Pregabalin Taro 100 mg
Pregabalin Taro 150 mg
Pregabalin Taro 200 mg
Pregabalin Taro 225 mg
Pregabalin Taro 300 mg
Capsules

Active ingredient
pregabalin 75, 100, 150, 200, 225, 300 mg

Inactive ingredients and allergens: see Section 2 under 'Important information about some of this medicine's ingredients', and Section 6 'Additional information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have further questions, consult your 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 intended for treatment of children and adolescents under 18 years of age.

1. What is this medicine intended for?

For treatment of neuropathic (neural) pain in adults, for treatment of fibromyalgia, and for treatment of generalized anxiety disorder (GAD) in adults.

Therapeutic group: A gamma-aminobutyric acid analog.

2. Before using this medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).

Special warnings about using this medicine
Contact your doctor before taking Pregabalin Taro

- Some patients taking Pregabalin Taro have reported allergic effects. These effects include swelling of the face, lips, tongue, and throat as well as diffuse skin rash. If you experience one or more of these effects, refer to your doctor immediately.
- Serious skin rashes including Stevens Johnson syndrome and toxic epidermal necrolysis have been reported in association with use of Pregabalin Taro. Stop using the medicine and refer your doctor immediately if you experience one or more of the symptoms related to the serious skin reactions described in section 4.

- The medicine may cause dizziness and somnolence, so elderly patients taking this medicine are at increased risk of falls and injuries. Use with caution until you get used to the medicine's effect on you.
- This medicine may cause blurring or loss of vision, or other changes in eyesight, most of which are temporary - inform your doctor immediately of any change in your vision.
- In some patients with diabetes, who gain weight while taking this medicine, the dosage of medicines for lowering blood sugar level may have to be adjusted.
- Certain side effects, such as sleepiness, may be more common, because patients with spinal injury may be taking other medicines to treat pain and spasticity, that have side effects similar to those of Pregabalin Taro, and their severity may increase when these are taken together.
- Heart failure has been reported in a number of patients who took this medicine, mostly in elderly patients with cardiovascular diseases. **Before you start taking this medicine, tell your doctor if you have a history of heart disease.**
- Several cases of kidney failure associated with treatment with this medicine have been reported. If you notice decreased urination during treatment with this medicine, report this to your doctor, as discontinuing treatment with this medicine may improve this.
- Thoughts of self-harm or suicidal thoughts or suicidal behavior have been reported in some patients who were treated with antiepileptic medicines such as Pregabalin Taro. If such thoughts or behavior occur at any point, refer to your doctor immediately.
- Combining Pregabalin Taro with other medicines (e.g., certain types of analgesics), which might cause constipation, may cause gastrointestinal problems (e.g. constipation, blocked or paralyzed bowel). Inform your doctor if you are constipated, particularly if you are prone to constipation.
- Before you start taking the medicine, inform your doctor if you are or have previously been dependent on or addicted to alcoholic beverages, drugs or any medicines. In this case, you may have a greater risk of becoming dependent on Pregabalin Taro.
- Convulsions may occur during treatment with the medicine or immediately after stopping it - inform your doctor immediately if you experience convulsions.
- Reduced brain function (encephalopathy) has been reported in a number of patients with other underlying conditions. Inform your doctor if you have a history of any medical condition with serious implications, including liver or kidney disease.
- There have been reports of breathing difficulties. If you have nervous system disorders, respiratory disorders, renal impairment, or you are older than 65, your doctor may prescribe you a different dosing regimen. Consult your doctor if you experience difficulty breathing or shallow breaths.

<u>Dependence</u>

Some people may become dependent on Pregabalin Taro (a need to keep taking the medicine). They may develop withdrawal effects when they stop using Pregabalin Taro (see section 3 "How to use this medicine?" and "If you stop taking the medicine"). If you have concerns that you may become dependent on Pregabalin Taro, it is important that you consult your doctor.

If you notice any of the following signs while taking Pregabalin Taro, it could be a sign that you have become dependent:

- You need to take the medicine for longer than prescribed for you
- You feel you need to take more than the dose prescribed for you

- You are using the medicine for reasons other than those for which it was prescribed for you
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, contact your doctor and consult them on the best treatment for you, including when you should stop taking the medicine and how to do this safely.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

Pregabalin Taro and certain other medicines may influence each other (interaction).

If Pregabalin Taro is taken together with certain medicines which have sedative effects (including opioids), it may potentiate these effects and could lead to respiratory failure, coma, and death. Intensity of dizziness, sleepiness, and reduced concentration may increase if Pregabalin Taro is taken concomitantly with:

Oxycodone - a pain-relief medicine.

Lorazepam - a medicine for treating anxiety.

Alcohol.

Pregabalin Taro may be taken with oral contraceptives.

Using this medicine and food

This medicine can be taken without regard to meals.

Using this medicine and alcohol consumption

Do not consume alcohol during the treatment with this medicine.

Pregnancy, breastfeeding, and fertility

Do not use Pregabalin Taro during pregnancy or breastfeeding unless your doctor has instructed you to do so after consultation.

Pregabalin use during the first 3 months of pregnancy may cause birth defects in the unborn child that require medical treatment. In a study reviewing data from women in Nordic countries who took pregabalin in the first 3 months of pregnancy, 6 in 100 babies had such birth defects. This compares to 4 in 100 babies born to women not treated with pregabalin in the study. Abnormalities of the face (orofacial clefts), the eyes, the nervous system (including the brain), kidneys and genitals have been reported.

Women who may become pregnant during the treatment with this medicine must use effective contraception.

Consult a doctor or pharmacist before using this medicine if you are pregnant or breastfeeding, if you suspect that you are pregnant or you are planning to become pregnant.

Driving and using machines

Do not drive or operate dangerous machines until you know how this medicine affects you, because using this medicine may cause dizziness, drowsiness or decreased concentration.

Important information about some of this medicine's ingredients
This medicine contains lactose monohydrate. If you have been told by your doctor that you are intolerant to certain sugars, consult your doctor before you start taking this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

Do not exceed the recommended dose.

Swallow the capsule whole. Do not open the capsule and disperse its contents because this method of administration has not been tested. Swallow the medicine with water.

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. You may feel drowsy, confused, worried, or restless from taking an overdose of Pregabalin Taro. Fits (convulsions) and unconsciousness (coma) have also been reported.

If you forget to take the medicine at the scheduled time
It is important to take this medicine at the same time every day. If you forget to take the medicine at the designated time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine
Even if your health improves, do not stop taking this medicine without consulting your doctor. If a decision is made to stop treatment, your doctor will explain how to do it. Treatment with this medicine must be stopped gradually over a period of at least a week.

After stopping treatment with this medicine (after long-term or short-term treatment), you may experience certain symptoms called withdrawal symptoms, including insomnia, headaches, nausea, anxiety, diarrhea, flu-like symptoms, convulsions, nervousness, depression, pain, sweating and dizziness. These effects may be more common and more severe if the medicine has been taken for a longer period of time. If you experience withdrawal symptoms, you should contact your doctor.

Do not take medicines in the dark! Check the label and dose every 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

Like all medicines, using Pregabalin Taro may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Refer to a doctor immediately if you experience swelling of the face or the tongue or a severe skin reaction (the skin reddens and becomes covered with blisters or peels).

Very common side effects: affect more than 1 in 10 people

- dizziness, drowsiness, headaches.

Common side effects: affect up to 1 in 10 people

- increased appetite.
- feeling of elation, confusion, disorientation, reduced sex drive, irritability.
- concentration or memory impairment, memory loss, clumsiness, tremor, difficulty with speaking, tingling feeling, numbness, sedation, lethargy, insomnia, fatigue, feeling abnormal.
- blurred vision, double vision.
- vertigo, balance disorders, falls.
- dry mouth, constipation, vomiting, flatulence, diarrhea, nausea, swollen abdomen.
- erection problems.
- swelling of the body including extremities.
- feeling drunk, abnormal style of walking.
- weight gain.
- muscle cramps, joint pain, back and limb pain.
- sore throat.

Uncommon side effects: affect up to 1 in 100 people

- loss of appetite, weight loss, decreased blood sugar level, increased blood sugar level.
- change in self-perception, restlessness, depression, agitation, mood swings, difficulty finding words, hallucinations, abnormal dreams, panic attacks, 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.
- vision changes including loss of peripheral vision, nystagmus, flashes of light, jerky movements, reduced reflexes, increased activity, dizziness on standing, skin sensitivity, loss of taste, burning sensation, tremor on moving, decreased consciousness, loss of consciousness, fainting, increased sensitivity to noise, feeling unwell.
- dry eyes, eye swelling or pain, weak eyes, watery eyes, eye irritation.
- heart rhythm disturbances, increased heart rate, low or high blood pressure, changes in heart beat, 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, urinary incontinence.
- weakness, thirst, chest tightness.
- changes in blood and liver function tests results (increase in blood creatine phosphokinase, increased liver enzymes, platelet count decreased, neutropenia, increase in blood creatinine, decrease in blood potassium).
- hypersensitivity, swollen face, itchiness, hives, runny nose, nosebleed, cough, snoring.
- painful menstrual periods.
- Cold hands and feet.

Rare side effects: affect up to 1 in 1,000 people

- abnormal sense of smell, swinging vision, change in depth perception, visual brightness, vision loss.
- dilated pupils, crossed eyes.
- cold sweat, irritation of the throat, swollen tongue.
- inflammation of the pancreas.
- difficulty in swallowing.
- slower or reduced movement of the body.
- difficulty with writing.
- edema in the abdominal area.
- fluid in the lungs.
- convulsions.
- changes in ECG which correspond to heart rhythm disorders.
- muscle damage.
- breast discharge, abnormal breast growth, breast growth in men.
- menstrual cycle disorders.
- kidney failure, reduced urine volume, urinary retention.
- decrease in white blood cell count in blood test.
- abnormal behavior, suicidal behavior, suicidal thoughts.
- allergic reactions (may manifest as breathing difficulties, inflammation of the eyes [keratitis] and a serious skin reaction characterized by reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, peeling skin, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens Johnson syndrome, toxic epidermal necrolysis).
- jaundice (yellowing of the skin and whites of the eyes).
- parkinsonism, that is symptoms resembling Parkinson's disease such as tremor, bradykinesia (decreased ability to move), and rigidity (muscle stiffness).

Very rare side effects: affect up to 1 in 10,000 people

- liver failure.
- inflammation of the liver (hepatitis).

Side effects of unknown frequency

- Becoming dependent on Pregabalin Taro

After stopping treatment (short or long-term) with Pregabalin Taro, you may experience certain symptoms called withdrawal symptoms (see "If you stop taking the medicine" in section 3).

Certain side effects, such as sleepiness, may be more common, because patients with spinal injury may be taking other medicines to treat pain and spasticity, that have side effects similar to those of Pregabalin Taro, and their severity may be increased when taken together.

The following side effects have been reported post-marketing: difficulty breathing and shallow breaths.

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. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of sight and reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use this 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 below 25˚C.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Capsule shell (gelatin, titanium dioxide), talc, lactose monohydrate, maize starch, imprinting ink (black iron oxide, shellac, propylene glycol, potassium hydroxide).
Pregabalin Taro capsules 75 mg, 100 mg, 200 mg, 225 mg, and 300 mg also contain red iron oxide.
Pregabalin Taro capsules 200 mg, and 225 mg also contain yellow iron oxide.

What the medicine looks like and contents of the pack:
Pregabalin Taro 75 mg: a white capsule with a brown-red cap. The number "75" is imprinted in black on the capsule body.
Pregabalin Taro 100 mg: a brown-red capsule with a brown-red cap. The number "100" is imprinted in black on the capsule body.
Pregabalin Taro 150 mg: a white capsule with a white cap. The number "150" is imprinted in black on the capsule body.
Pregabalin Taro 200 mg: a pink-orange capsule with a pink-orange cap. The number "200" is imprinted in black on the capsule body.
Pregabalin Taro 225 mg: a white capsule with a pink-orange cap. The number "225" is imprinted in black on the capsule body.
Pregabalin Taro 300 mg: a white capsule with a brown-red cap. The number "300" is imprinted in black on the capsule body.

This medicine is supplied in packs of 14, 28, 56 capsules.
Not all pack sizes may be marketed.

Manufacturer's name and address: Sofarimex – Industria Quimica e Farmaceutica, S.A, Cacem, Portugal

Registration holder's name and address: Taro International Ltd., 14 Hakitor St., Haifa Bay 2624761.

Revised in November 2022 according to MOH guidelines.

Registration numbers of the medicines in the National Drug Registry of the Ministry of Health:
Pregabalin Taro 75 mg: 158-25-34763-00
Pregabalin Taro 100 mg: 158-26-34762-00
Pregabalin Taro 150 mg: 158-27-34761-00

Pregabalin Taro 200 mg: 158-28-34760-00
Pregabalin Taro 225 mg: 158-29-34759-00
Pregabalin Taro 300 mg: 158-30-34740-00