Package leaflet: Information for the user

Pragiola 75 mg capsules
pregabalin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pragiola is and what it is used for

Pragiola belongs to a group of medicines used to treat epilepsy, neuropathic pain and generalised anxiety disorder (GAD) in adults.

Peripheral and central neuropathic pain: Pragiola is used to treat long-lasting pain caused by damage to the nerves. A variety of diseases can cause peripheral neuropathic pain, such as diabetes or shingles. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles. Peripheral and central neuropathic pain may also be associated with mood changes, sleep disturbance, fatigue (tiredness), and can have an impact on physical and social functioning and overall quality of life.

Epilepsy: Pragiola is used to treat certain forms of epilepsy (partial seizures with or without secondary generalisation) in adults. Your doctor will prescribe Pragiola for you to help treat your epilepsy when your usual treatment is no longer controlling your condition. You should take Pragiola in addition to your current treatment. Pragiola is not intended to be used alone, but should always be used in combination with other anti-epileptic medicines.

Generalised anxiety disorder: Pragiola is used to treat generalised anxiety disorder (GAD). The symptoms of GAD are prolonged excessive anxiety and worry that are difficult to control. GAD can also cause restlessness or feeling keyed up or on edge, being easily tired, having difficulty concentrating or mind going blank, feeling irritable, having muscle tension or sleep disturbance. This is different to the stresses and strains of everyday life.

2. What you need to know before you take Pragiola

Do not take Pragiola
- if you are allergic to pregabalin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Pragiola.
- Some patients taking pregabalin 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 doctor immediately.
- Serious skin rash has been reported in association with pregabalin, including Stevens-Johnson syndrome and toxic epidermal necrolysis. Stop the treatment with pregabalin and immediately seek medical attention if you notice any of the symptoms associated with these serious skin reactions described in section 4.
- Pregabalin 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.
- Pragiola 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 Pragiola may need a change 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 Pragiola and the severity of these effects may be increased when the medicines are taken together.
- There have been reports of heart failure in some patients who were taking pregabalin; these patients were mostly older 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 who were taking pregabalin. If while taking Pragiola you notice decreased urination, you should tell your doctor as stopping the medicine may improve this.
- Some patients treated with anti-epileptics such as pregabalin have had thoughts of harming or killing themselves or have manifested a suicidal behaviour. If at any time you have these thoughts or manifest such a behaviour, immediately contact your doctor.
- When Pragiola 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 large 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 prescription or illegal drug abuse or dependence; this may mean you have a higher risk of becoming addicted to pregabalin.
- There have been reports of convulsions when taking pregabalin or shortly after stopping it. If you experience convulsions, contact your doctor immediately.
- There have been reports of reduction in brain function (encephalopathy) in some patients taking pregabalin while having other conditions. Tell your doctor if you have a history of any serious medical condition, including liver or kidney disease.

There have been reports of breathing difficulties. If you have nervous system disorders, respiratory disorders, renal impairment, or if you are older than 65, your doctor may prescribe a different dosing regimen. Contact your doctor if you find it hard to breathe or your breathing

is shallow.
Dependence

Some people may develop dependence on Pragiola (the need to continue taking the medicine). These people may experience withdrawal symptoms when they stop using Pragiola (see section 3, “How to take Pragiola” and “If you stop taking Pragiola”). If you are concerned that you may develop dependence on Pragiola, it is important that you talk to your doctor.

If you notice any of the following symptoms while still taking Pragiola, it might be a sign that you have developed dependence:
- You need to take the medicine for a longer period of time than recommended by the doctor prescribing it to you.
- You feel you need to take more than the recommended dose.
- You use the medicine for other reasons than prescribed.
- You have tried repeatedly and unsuccessfully to quit or control the use of the medicine.
- When stopping the medicine, you feel unwell and you start feeling better once you resume taking the medicine.

If you notice any of these, contact your doctor in order to discuss the best course of treatment for you, including when it is suitable for you to stop the administration and how to do it safely.

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

Other medicines and Pragiola
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Pragiola and certain other medicines may influence each other (interaction). When taken with certain medicines which have sedative effects (including opioids), Pragiola may potentiate these effects and could lead to respiratory failure, coma and death. The degree of dizziness, sleepiness and decreased concentration may be increased if Pragiola is taken together with other medicines containing:
- Oxycodone (used as a pain-killer)
- Lorazepam (used for treating anxiety)
- Alcohol.

Pragiola may be taken with oral contraceptives.

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

Pregnancy, breast-feeding and fertility
Pragiola should not be taken during pregnancy or when breast-feeding, unless you are told otherwise by your doctor. The use of pregabalin during the first 3 months of pregnancy may cause birth defects to the unborn baby, which require medical treatment. During one study that reviewed data from Nordic women who took pregabalin during the first 3 months of pregnancy, 6 out of 100 newborn babies had such birth defects. This measure can be compared with the 4 out of 100 newborn babies seen in the women who had not been treated with pregabalin during the study. Defects have been reported in the face area (orofacial clefts), eyes, nervous system (including in the brain), kidneys and genitals.

Women of child-bearing potential must use birth control. 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
Pragiola may cause dizziness, sleepiness and decreased concentration (attention). You should not drive, operate complex machinery or engage in other potentially hazardous activities until you know how you react to this medicine.

3. How to take Pragiola

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will determine what dose is appropriate for you.
Pragiola is for oral use only.

Peripheral and central neuropathic pain, epilepsy or generalised anxiety disorder
- 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 Pragiola either twice or three times a day. For the twice-daily dosing regimen, take Pragiola once in the morning and once in the evening, at about the same time each day. For three-times-daily dosing regimen, take Pragiola 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 Pragiola is too strong or too weak, talk to your doctor or pharmacist.

If you are an elderly person (over 65 years of age), you should take Pragiola as shown above, unless you have problems with your kidneys. Your doctor may prescribe a different dosing schedule and/or different doses if you have problems with your kidneys.

Swallow the capsules whole with water.

Continue taking Pragiola for the entire duration prescribed by your doctor.

If you take more Pragiola than you should
Call your doctor or go to the nearest hospital emergency unit immediately. Take the carton or bottle of Pragiola capsules with you. You may feel sleepy, confused, agitated, or restless as a result of taking more Pragiola than you should. Seizures and loss of consciousness (coma) have been reported.

If you forget to take Pragiola
It is important to take your Pragiola 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 Pragiola
Do not abruptly stop taking Pragiola. If you want top stop taking Pragiola, talk to your doctor first. They will tell you how to do this. If the treatment needs to be stopped, it should be done gradually over a period of at least 1 week.

You must be aware that, after stopping the long- or short-term treatment with Pragiola, you may experience certain side effects, the so-called withdrawal symptoms. These symptoms include trouble sleeping, headache, nausea, feeling restless, diarrhoea, flu-like symptoms, convulsions, nervousness, depression, pain, sweating, and dizziness. These symptoms may be more common or more severe if you have been taking Pragiola for a longer period of time. If you experience withdrawal symptoms, you must talk to your doctor.

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.

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.

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

Common side effects: may affect up to 1 in 10 people
- Increased appetite.
- Feeling of elation, confusion, disorientation, decrease in sexual interest, irritability.
- Attention disorders, clumsiness, memory impairment, loss of memory, tremor,

difficulty speaking, tingling, numbness, sedation, lethargy, insomnia, tiredness, feeling unwell.
- Blurred vision, double vision.
- Vertigo, problems with balance, falls.
- Dry mouth, constipation, vomiting, flatulence, diarrhoea, nausea, swollen abdomen.
- Difficulties with erection.
- Swelling of the body, including extremities.
- Feeling drunk, abnormal gait.
- Weight gain.
- Muscle cramps, joint pain, back pain, pain in limbs.
- Sore throat.

Uncommon side effects: may affect up to 1 in 100 people
- Loss of appetite, weight loss, low blood sugar, high blood sugar.
- Personality changes, restlessness, depression, agitation, emotional instability, difficulty finding words, hallucinations, abnormal dreams, panic attack, apathy, aggression, elevated mood, mental impairment, difficulty thinking, increase in sexual interest, problems with the sexual function 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, hyperactivity, dizziness on standing, increased skin sensitivity, loss of taste, burning sensation, tremor on movement, decreased consciousness, loss of consciousness, fainting, increased sensitivity to noise, general malaise.
- Dry eyes, increased tearing, eye pain, short-sightedness (poor vision), “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, numbness 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 test results (increased blood creatinine phosphokinase, increased alanine aminotransferase, increased aspartate aminotransferase, decreased platelet count, neutropenia, increased blood creatinine, decreased blood potassium).
- Hypersensitivity, swollen face, itchiness, hives, runny nose, nosebleed, cough, snoring.
- Painful menstrual periods.
- Coldness of hands and feet.

Rare side effects: may affect up to 1 in 1,000 people
- Altered 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 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 the electrical activity of the heart (ECG), which are consistent with heart rhythm disturbances.
- Muscle breakdown.
- Breast discharge, abnormal breast growth, breast growth in males.
- Interrupted menstrual periods.
- Renal impairment, reduced urine volume, urinary retention.
- Decrease in white blood cell count.
- Inappropriate behaviour, suicidal behaviour, suicidal thoughts.
- Allergic reactions which may include difficulty breathing, inflammation of the eyes (keratitis) and a serious skin reaction characterized by flat, bullseye-shaped or circular, red spots on the trunk, often with blisters at the centre, peeling skin, sores in the mouth, throat, nose, genitals and eyes. These serious skin rashes may be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Jaundice (yellowing of the skin and eyes).
- Parkinsonism, that is, Parkinson's disease-like symptoms; such as tremor, bradykinesia (decreased ability to move) and stiffness (lack of muscle flexibility).

Very rare side effects: may affect up to 1 in 10,000 people
- Impaired liver function.
- Hepatitis (inflammation of the liver).

Not known: frequency cannot be estimated from the available data
- Becoming dependent on Pragiola ("drug addiction").
  After stopping the long- or short-term treatment with Pragiola, you may experience certain side effects, the so-called withdrawal symptoms (see "If you stop taking Pragiola").

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 Pragiola, and the severity of these effects may be increased when these medicines are taken together.

The following side effects have been reported as part of the post-marketing experience: Difficulty breathing, shallow breathing.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to National Agency for Medicines and Medical Devices of Romania

48 Aviator Sanatescu St., Sector 1

Bucharest 011478 - RO

Email: adr@anm.ro

Website: www.anm.ro

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pragiola

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

Store below 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. Contents of the pack and other information

What Pragiola contains
- The active substance is pregabalin. Each capsule contains 75 mg, of pregabalin.
- The other ingredients are: pregelatinised maize starch, talc (E553b) in the *capsule content*.
- The other ingredients of the 75 mg capsules are: titanium dioxide (E171), gelatin, yellow iron oxide (E172), black printing ink (shellac (E904), black iron oxide (E172), propylene glycol (E1520)) in the capsule shell.

What Pragiola looks like and contents of the pack
75 mg capsules: brownish-yellow capsule body, brownish-yellow cap. Capsule cap is imprinted with P75 with black printing ink. Capsule content is white to off-white powder. Capsule length: 13.8 – 14.8 mm.
Pragiola 75 mg is available in cartons of 14, 28, 30, 56, 60, 84, 90, 98 and 100 capsules in blister packs.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturers
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

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Name of the Member State	Name of the medicinal product
Bulgaria, Cyprus, Croatia, Estonia, Greece, Latvia, Lithuania, Malta, Poland, Czech Republic, Slovakia, Romania, Slovenia, Hungary	**Pragiola**

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