Package leaflet: Information for the user

Pregabalin Teva 25 mg Capsules, hard
Pregabalin Teva 50 mg Capsules, hard
Pregabalin Teva 75 mg Capsules, hard
Pregabalin Teva 100 mg Capsules, hard
Pregabalin Teva 150 mg Capsules, hard
Pregabalin Teva 200 mg Capsules, hard
Pregabalin Teva 225 mg Capsules, hard
Pregabalin Teva 300 mg Capsules, hard

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 Pregabalin Teva is and what it is used for

Pregabalin Teva belongs to a group of medicines used to treat epilepsy and Generalised Anxiety Disorder (GAD) in adults.

Epilepsy: Pregabalin Teva is used to treat a certain form of epilepsy (partial seizures with or without secondary generalisation) in adults. Your doctor will prescribe Pregabalin Teva for you to help treat your epilepsy when your current treatment is not controlling your condition. You should take Pregabalin Teva in addition to your current treatment. Pregabalin Teva is not intended to be used alone, but should always be used in combination with other anti-epileptic treatment.

Generalised Anxiety Disorder: Pregabalin Teva 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 fatigued (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 Pregabalin Teva

Do not take Pregabalin Teva:
- 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 Pregabalin Teva.

- 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.

- Pregabalin has been associated with dizziness and drowsiness (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.

- Pregabalin 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 (see section 4).

- 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, stiff or rigid muscles (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 pregabalin; 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 pregabalin. If while taking Pregabalin Teva 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 pregabalin have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

- When Pregabalin Teva 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 pregabalin or shortly after stopping pregabalin. If you experience a convulsion, contact your doctor immediately.

- There have been reports of reduction in brain function (encephalopathy) in some patients taking pregabalin 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, Pregabalin Teva should not be used in this age group.

Other medicines and Pregabalin Teva

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

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

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

Pregabalin Teva may be taken with oral contraceptives.

Pregabalin Teva with food, drink and alcohol
It is advised not to drink alcohol while taking Pregabalin Teva.

Pregnancy and breast-feeding
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.

Pregabalin Teva 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.

Driving and using machines
Pregabalin Teva may cause 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 Pregabalin Teva

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.

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 Pregabalin Teva either twice or three times a day. For twice a day take Pregabalin Teva once in the morning and once in the evening, at about the same time each day. For three times a day take Pregabalin Teva 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 Pregabalin Teva 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 Pregabalin Teva 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.

Pregabalin Teva is for oral use only.

Swallow the capsule whole with water.
Pregabalin Teva capsules may be taken with or without food

Continue taking Pregabalin Teva until your doctor tells you to stop.

If you take more Pregabalin Teva than you should
Call your doctor or go to the nearest hospital emergency unit immediately. Take your pack of Pregabalin Teva capsules with you. You may feel sleepy, confused, agitated, or restless as a result of taking more Pregabalin Teva than you should.

If you forget to take Pregabalin Teva
It is important to take your Pregabalin Teva 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 Pregabalin Teva
Do NOT stop taking Pregabalin Teva 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 Pregabalin Teva treatment, you need to know that you may experience certain side effects. These include, trouble sleeping, headache, feeling sick (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 Pregabalin Teva 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, tiredness (fatigue), feeling abnormal
- Blurred vision, double vision
- Vertigo, problems with balance, fall
- Dry mouth, constipation, vomiting, flatulence, diarrhoea, feeling sick (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 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
- 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 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, 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, neutropenia, 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 1000 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 characterised by rash, blisters, peeling skin and pain)

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, spasticity, that have similar side effects to pregabalin and the severity of these effects may be increased when taken together.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie

Malta
ADR Reporting
www.medicinesauthority.gov.mt/adrportal

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

5. How to store Pregabalin Teva

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 blister, carton or bottle. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Pregabalin Teva contains
- The active substance is pregabalin. Each capsule, hard contains 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg or 300 mg of pregabalin.
- The other ingredients are: mannitol, pregelatinised maize starch, talc, titanium dioxide (E171), yellow iron oxide (E172) (25, 50, 75, 150, 225 and 300 mg capsules), red iron oxide (E172) (75, 100, 200, 225 and 300 mg capsules), gelatin and black ink (which contains shellac, propylene glycol, black iron oxide (E172) and potassium hydroxide).

What Pregabalin Teva looks like and contents of the pack
Pregabalin Teva 25 mg are ivory opaque hard gelatine size 3 capsules with overall closed length 15.9 mm ± 0.3 mm, imprinted by black sign 25 on capsule body.
Pregabalin Teva 50 mg are ivory opaque hard gelatine size 2 capsules with overall closed length 18.0 mm ± 0.3 mm, imprinted by radial black band on capsule cap and black sign 50 and radial black band on capsule body.
Pregabalin Teva 75 mg are opaque hard gelatine size 3 capsules with overall closed length 15.9 mm ± 0.3 mm, with pink cap and ivory body imprinted by black sign 75.
Pregabalin Teva 100 mg are pink opaque hard gelatine size 2 capsules with overall closed length 18.0 mm ± 0.3 mm, imprinted by black sign 100 on capsule body.
Pregabalin Teva 150 mg are ivory opaque hard gelatine size 2 capsules with overall closed length 18.0 mm ± 0.3 mm, imprinted by black sign 150 on capsule body.

Pregabalin Teva 200 mg are flesh opaque hard gelatine size 1 capsules with overall closed length 19.4 mm ± 0.3 mm, imprinted by black sign 200 on capsule body.
Pregabalin Teva 225 mg are opaque hard gelatine size 1 capsules with overall closed length 19.4 mm ± 0.3 mm,with flesh cap and ivory body imprinted by black sign 225.
Pregabalin Teva 300 mg are opaque hard gelatine size 0 capsules with overall closed length 21.7 mm ± 0.3 mm, with pink cap and ivory body imprinted by black sign 300.

For 25 mg capsules:
Pregabalin Teva capsules are packed in PVC-Alu or unit dose blisters of 14, 14x1, 21, 21x1, 50x1, 56, 56x1, 60, 84, 84x1, 90, 100, 100x1, or 120 capsules.

For 50 mg capsules:
Pregabalin Teva capsules are packed in PVC-Alu or unit dose blisters of 14, 21, 21x1, 56, 56x1, 60, 84, 84x1, 100, 100x1, or 120 capsules.

For 75 mg capsules:
Pregabalin Teva capsules are packed in PVC-Alu or unit dose blisters of 14, 14x1, 50x1, 56, 56x1, 60, 70, 90, 100 ,100x1, or 120 capsules.
Additionally, Pregabalin Teva capsules are packed in HDPE bottles with PP closure containing 200 capsules.

For 100 mg capsules:
Pregabalin Teva capsules are packed in PVC-Alu blisters or unit dose blisters of 14, 21, 21x1, 56, 56x1, 84, 84x1, 100, 100x1, or 120 capsules.

For 150 mg capsules:
Pregabalin Teva capsules are packed in PVC-Alu or unit dose blisters of 14, 14x1, 50x1, 56, 56x1, 60, 90, 100, 100x1, 120, 168, 168x1 or 200x1 capsules.
Additionally, Pregabalin Teva capsules are packed in HDPE bottles with PP closure containing 200 capsules.

For 200 mg capsules:
Pregabalin Teva capsules are packed in PVC-Alu blisters or unit dose blisters of 14, 21, 21x1, 84, 84x1, 100, 100x1, or 120 capsules.

For 225 mg capsules:
Pregabalin Teva capsules are packed in PVC-Alu blisters or unit dose blisters of 14, 14x1, 56, 56x1, 60, 100, 100x1, or 120 capsules.
Additionally, Pregabalin Teva capsules are packed in HDPE bottles with PP closure containing 200 capsules.

For 300 mg capsules:
Pregabalin Teva capsules are packed in PVC-Alu or unit dose blisters of 14, 14x1, 50x1, 56, 56x1, 60, 84, 84x1, 90, 100, 100x1, 120, 168, 168x1or 200x1 capsules.
Additionally, Pregabalin Teva capsules are packed in HDPE bottles with PP closure containing 200 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Teva B.V.
Swensweg 5

2031GA Haarlem
Netherlands

Manufacturer
TEVA UK Ltd
Brampton Road
Hampden Park
Eastbourne
East Sussex
BN22 9AG
United Kingdom

Merckle GmbH
Ludwig-Merckle-Straße 3
Blaubeuren
89143
Germany

PLIVA Hrvatska d.o.o. (PLIVA Croatia Ltd.)
Prilaz baruna Filipovica 25
Zagreb
10000
Croatia

This medicinal product is authorised in the Member States of the EEA under the following names:
Belgium: Pregabaline Teva

Bulgaria: Прегабалин Тева

Cyprus, Greece: Pregabalin/Teva

Czech Republic, Estonia, Denmark, Germany, Ireland, Italy, Luxembourg, Lithuania, Latvia, Malta, Netherlands, Poland, Sweden, Slovenia, Slovakia, United Kingdom : Pregabalin Teva

Spain: Pregabalina Tevagen

France: Pregabaline Teva Santé

Croatia: Pregabalin Pliva

Hungary: Pregabalin-Teva

Portugal: Pregabalina Zidrium

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