

After stopping a short or long-term treatment with Pregabalin Teva, you need to know that you may experience certain side effects, so-called withdrawal effects. These effects include, trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, convulsions,

nervousness, depression, thoughts of harming or killing yourself, pain, sweating and dizziness. These effects may occur more commonly or severely if you have been taking Pregabalin Teva for a longer period of time. If you experience withdrawal effects, you should contact 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.

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 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 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, suicidal behaviour, suicidal thoughts
- Allergic reactions which may include difficulty breathing, inflammation of the eyes (keratitis) and a serious skin reactions characterised by reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, 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 eyes)
- Parkinsonism, that is symptoms resembling Parkinson's disease; such as tremor, bradykinesia (decreased ability to move), and rigidity (muscle stiffness)

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

- Liver failure
- Hepatitis (inflammation of the liver)

Not known: frequency cannot be estimated from the available data

- Becoming dependent on Pregabalin Teva ('drug dependence')

After stopping a short or long-term treatment with Pregabalin Teva, you need to know that you may experience certain side effects, so-called withdrawal effects (see "If you stop taking Pregabalin Teva").

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.

The following adverse reaction has been reported in the postmarketing experience: Trouble breathing, shallow breaths.

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

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 via the Yellow Card Scheme Website at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card on the Google Play or Apple App Store. 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 25 mg capsule, hard contains 25 mg pregabalin.
- Each 50 mg capsule, hard contains 50 mg pregabalin.
- Each 75 mg capsule, hard contains 75 mg pregabalin.
- Each 100 mg capsule, hard contains 100 mg pregabalin.
- Each 150 mg capsule, hard contains 150 mg pregabalin.
- Each 200 mg capsule, hard contains 200 mg pregabalin.
- Each 225 mg capsule, hard contains 225 mg pregabalin.
- Each 300 mg capsule, hard contains 300 mg 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, 168x1 or 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

TEVA UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer

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