PREGABALIN TEVA 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg AND 300 mg CAPSULES, HARD

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Read all of this leaflet carefully before you start taking this medicine because it contains important

- The state of the state
- 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:

- What Pregabalin Teva is and what it is used for
 What you need to know before you take
 Pregabalin Teva
 How to take Pregabalin Teva
 Possible side effects
 How to store Pregabalin Teva
 Contents of the pack and other information



WHAT PREGABALIN TEVA IS AND WHAT IT IS USED FOR

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

Generalised Anxiety Disorder (GAD) in adults.

Peripheral and central neuropathic pain:

Pregabalin Teva 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: Pregabalin Teva is used to treat a certain

and social functioning and overall quality of life.

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.

WHAT YOU NEED TO KNOW BEFORE YOU TAKE PREGABALIN TEVA

Do NOT 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).

- igredients of this medicine disted in section.

 Varnings and precautions
 alk to your doctor or pharmacist before taking
 regabalin Teva.

 Some patients taking pregabalin have reported
 symptoms suggesting an allergic reaction. These
- Namings and precautions
 lalk 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.

 Serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis
 have been reported in association with
 pregabalin. Stop using pregabalin and seek
 medical attention immediately if you notice
 any of the symptoms related to 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.
 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.
 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 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.
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 patients when taking pregabalin; these patients
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 patients when taking pregabalin; the

- disease.
 There have been reports of breathing difficulties.
 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. Contact your doctor if you
 experience trouble breathing or shallow breaths.

Dependence

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

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

You need to take the medicine for longer than

- Advised by your prescriber
 You feel you need to take more than the
 recommended dose

You feel you need to take more than the recommended dose
You are using the medicine for reasons other than prescribed
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, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to do this safely.

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

Other medicines and Pregabalin Teva

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

medicines.
Pregabalin Teva and certain other medicines may influence each other (interaction). When taken with certain other medicines, which have sedative effects (including opioids), Pregabalin Teva 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 Pregabalin Teva is taken together with medicines 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

Pregabalin Teva may be taken with or without food. It is advised NOT to drink alcohol while taking

lt is advisea ויסיו Pregabalin Teva. Pregnancy and breast-feeding

Pregnancy and breast-feeding
Pregabalin Teva should NOT be taken during
pregnancy or when breast-feeding, unless you are
told otherwise by your doctor. 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 babies in every 100 had
such birth defects. This compares to 4 babies in
every 100 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.

Effective contraception must be used by women of
childbearing potential.

If you are pregnant or breast-feeding, think you may

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
Pregabalin Teva 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 PREGABALIN TEVA

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

. Your doctor will determine what dose is appropriate Pregabalin Teva is for oral use only

Peripheral and central neuropathic pain, epilepsy or Generalised Anxiety Disorder:

Take the number of capsules as instructed by

- 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 afternoon and once in the morning, once in the afternoon and once in the evening, at about the same time each day.

once in the evening, at about the standard 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 vour kidnevs

Swallow the capsule whole with water.
Continue taking Pregabalin Teva until your doctor

tells you to stop 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. Fits and unconsciousness (coma) have also been reported.

reported.

reported.

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.

flyou stop taking Pregabalin Teva
Do not suddenly stop taking Pregabalin Teva. If you want to stop taking Pregabalin Teva, discuss this with your doctor first. They will tell you how to do this. If your treatment is stopped it should be done gradually over a minimum of 1 week.

gradually over a minimum of I week.
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 yourslef, 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

- 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

- 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 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, platelet count decreased, neutropenia, increase in blood creatinine, decrease in blood pressurine, decrease in blood pressurine, decrease in blood pressitine, decrease in blood pressitine, decrease in blood pressitine, 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 bright

- Cooness or nands and reet.
 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

- 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)
 Parkinson's disease; such as tremor, bradykinesia
 (decreased ability to move), and rigidity (muscle
 stiffness)

 fery rare: may affect up to 1 in 10,000 people
 Liver failure

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')

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").

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

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 in 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

Do not throw away any medicines via wastewate 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 225 mg capsule, hard contains 300 mg pregabalin.
 Each 300 mg capsule, hard contains 300 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

Mydroxide).

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 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 15.9 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 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.

18.0 mm ± 0.3 mm, imprinted 2, 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

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.

84XI, 10U, 10UX1 or 12U capsules. Pregabalin Teva capsules are packed in PVC-Alu or unit dose blisters of 14, 14XI, 50XI, 56, 56XI, 60, 70, 90, 100, 100XI or 120 capsules. Additionally, Pregabalin Teva capsules are packed in HDPE bottles with PP closure containing 200

capsules

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:
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

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

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