

Package leaflet: Information for the user

Pregabalin Zentiva k.s. 25 mg hard capsules
Pregabalin Zentiva k.s. 50 mg hard capsules
Pregabalin Zentiva k.s. 75 mg hard capsules
Pregabalin Zentiva k.s. 100 mg hard capsules
Pregabalin Zentiva k.s. 150 mg hard capsules
Pregabalin Zentiva k.s. 200 mg hard capsules
Pregabalin Zentiva k.s. 225 mg hard capsules
Pregabalin Zentiva k.s. 300 mg hard 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 Pregabalin Zentiva k.s. is and what it is used for
2. What you need to know before you take Pregabalin Zentiva k.s.
3. How to take Pregabalin Zentiva k.s.
4. Possible side effects
5. How to store Pregabalin Zentiva k.s.
6. Contents of the pack and other information

1. What Pregabalin Zentiva k.s. is and what it is used for

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

Peripheral and central neuropathic pain

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

Generalised anxiety disorder

Pregabalin Zentiva k.s. 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 Zentiva k.s.

Do not take Pregabalin Zentiva k.s.

- 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 Zentiva k.s.

- 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 physician immediately.
- 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.**
- There have been reports of kidney failure in some patients when taking pregabalin. If while taking Pregabalin Zentiva k.s. 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 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.
- 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.

Children and adolescents

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

Other medicines and Pregabalin Zentiva k.s.

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

Pregabalin Zentiva k.s. and certain other medicines may influence each other (interaction). When taken with certain other medicines which have sedative effects (including opioids), pregabalin 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 is taken together with medicines containing:

- oxycodone (used as a pain-killer).
- lorazepam (used for treating anxiety).
- alcohol.

Pregabalin Zentiva k.s. may be taken with oral contraceptives.

Pregabalin Zentiva k.s. with food, drink and alcohol

Pregabalin Zentiva k.s. hard capsules may be taken with or without food.

It is advised not to drink alcohol while taking Pregabalin Zentiva k.s..

Pregnancy and breast-feeding

Pregabalin Zentiva k.s. 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. 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 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.

Pregabalin Zentiva k.s. contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Pregabalin Zentiva k.s.

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.

Pregabalin Zentiva k.s. is for oral use only.

Peripheral and central neuropathic pain, epilepsy or generalised anxiety disorder

Take the number of hard 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 Zentiva k.s. either twice or three times a day. For twice a day take Pregabalin Zentiva k.s. once in the morning and once in the evening, at about the same time each day. For three times a day take Pregabalin Zentiva k.s. 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 Zentiva k.s. 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 Zentiva k.s. 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.

Swallow the capsule whole with water.

Continue taking Pregabalin Zentiva k.s. until your doctor tells you to stop.

If you take more Pregabalin Zentiva k.s. than you should

Call your doctor or go to the nearest hospital emergency unit immediately. Take your box of Pregabalin Zentiva k.s. hard capsules with you. You may feel sleepy, confused, agitated, or restless as a result of taking more Pregabalin Zentiva k.s. than you should. Fits have also been reported.

If you forget to take Pregabalin Zentiva k.s.

It is important to take your Pregabalin Zentiva k.s. hard 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 Zentiva k.s.

Do not stop taking Pregabalin Zentiva k.s. 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 treatment, you need to know that you may experience certain side effects. These include, trouble sleeping, headache, 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 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, 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 attack, 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 heartbeat, 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 aminotransferase 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.
- Allergic reactions (which may include difficulty breathing, inflammation of the eyes (keratitis) and a serious skin reaction characterized by rash, blisters, peeling skin and pain).
- Jaundice (yellowing of the skin and eyes).

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

- Liver failure.
- Hepatitis (inflammation of the liver).

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.

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

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

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 national reporting system listed below.

Ireland
HPRA Pharmacovigilance
www.hpra.ie

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

5. How to store Pregabalin Zentiva k.s.

Keep this medicine out of the sight and reach of children.

Do not store above 30 °C.

Do not use this medicine after the expiry date which is stated on the blister and carton after “EXP”.

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

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 Zentiva k.s. contains

- The active substance is pregabalin. Each hard capsule contains 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg or 300 mg of pregabalin.
- The other ingredients are lactose monohydrate, pregelatinized maize starch, talc, titanium dioxide (E171), gelatin, shellac, black iron oxide (E172).

The 50 mg capsules also contain propylene glycol, strong ammonia solution, potassium hydroxide.

The 25 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, 300 mg capsules also contain polyethylene glycol.

The 75 mg, 100 mg, 200 mg, 225 mg and 300 mg capsules also contain red iron oxide (E172), yellow iron oxide (E172).

What Pregabalin Zentiva k.s. looks like and contents of the pack	
25 mg capsules	Light grey cap and light grey body; approx. 15,9 mm in length, hard gelatin capsule with imprinting “25”, containing almost white powder.
50 mg capsules	Light grey cap and light grey body; approx. 14,3 mm in length, hard gelatin capsule with imprinting “50”, containing almost white powder.
75 mg capsules	Red cap and light grey body; approx. 14,3 mm in length, hard gelatin capsule with imprinting “75”, containing almost white powder.
100 mg capsules	Red cap and red body; approx. 15,9 mm in length, hard gelatin capsule with imprinting “100”, containing almost white powder.
150 mg capsules	Light grey cap and light grey body; approx. 18,0 mm in length, hard gelatin capsule with imprinting “150”, containing almost white powder.
200 mg capsules	Flesh opaque cap and Flesh opaque body; approx. 19,4 mm in length, hard gelatin capsule with imprinting “200”, containing almost white powder.
225 mg capsules	Flesh opaque cap and light grey body; approx. 19,4 mm in length, hard gelatin capsule with imprinting “225”, containing almost white powder.
300 mg capsules	Red cap and light grey body; approx. 21,7 mm in length, hard gelatin capsule with imprinting “300”, containing almost white powder.

Pregabalin Zentiva k.s. 25 mg hard capsules are packed into alu/alu (OPA/alu/PVC/alu) blisters as primary packaging.

Pregabalin Zentiva k.s. 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg hard capsules are packed into PVC/alu blisters as primary packaging.

Pregabalin Zentiva k.s. 25 mg and 50 mg is available in pack of 14, 21, 56, 84, 98 and 100 hard capsules.

Pregabalin Zentiva k.s. 75 mg, 150 mg, 225 mg and 300 mg is available in pack of 14, 56, 98 and 100 hard capsules.

Pregabalin Zentiva k.s. 100 mg, 200 mg is available in pack of 21, 84, 98 and 100 hard capsules.

Not all pack sizes may be marketed.

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Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.