

Pregabalin Rosemont 20mg/ml Oral Solution

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 Rosemont is and what it is used for
2. What you need to know before you take Pregabalin Rosemont
3. How to take Pregabalin Rosemont
4. Possible side effects
5. How to store Pregabalin Rosemont
6. Contents of the pack and other information

1. What Pregabalin Rosemont is and what it is used for

Pregabalin 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 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 is used to treat a certain form of epilepsy (partial seizures with or without secondary generalisation- epileptic fits starting on one specific part of the brain) in adults. Your doctor will prescribe pregabalin for you to help treat your epilepsy when your current treatment is not controlling your condition. You should take pregabalin in addition to your current treatment.

Pregabalin is not intended to be used alone, but should always be used in combination with other anti-epileptic treatment.

Generalised Anxiety Disorder

Pregabalin 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 Rosemont

Do not take Pregabalin Rosemont

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.

- 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 you notice decreased urination, you should tell your doctor as stopping the medicine may improve this.
- Some patients being treated with anti-epileptics such as pregabalin have had thoughts of harming or killing themselves or shown suicidal behaviour. If at any time you have these thoughts or shown such behaviour, 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 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.
- Serious skin rashes including Stevens-Johnson syndrome, 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.

Dependence

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

If you notice any of the following signs whilst taking Pregabalin, 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 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 should not be used in this age group.

Other medicines and Pregabalin

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

Pregabalin 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 may be taken with oral contraceptives.

Pregabalin Rosemont with food, drink and alcohol

Pregabalin may be taken with or without food.

It is advised not to drink alcohol while taking Pregabalin.

Pregnancy, breast-feeding and fertility

Pregabalin 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 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 Rosemont contains:

- methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216), which may cause allergic reactions (possibly delayed).
- This medicine contains less than 1mmol sodium (23mg) per 1ml dose, that is to say essentially 'sodium-free'.

3. How to take Pregabalin Rosemont

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.

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

- Take the solution as instructed by your doctor.
- The dose, which has been adjusted for you and your condition, will generally be between 150 mg (7.5 ml) and 600 mg (30 ml) each day.
- Your doctor will tell you to take this medicine either twice or three times a day. For twice a day take this medicine once in the morning and once in the evening, at about the same time each day. For three times a day take this medicine 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 this medicine 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 this medicine normally except if you have problems with your kidneys.

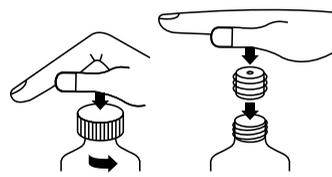
Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

Continue taking this medicine until your doctor tells you to stop.

Administration and instructions for use

Pregabalin Rosemont is for oral use only.

1. Open the bottle: Press downward on the cap and turn it counter-clockwise (Figure 1).
2. **First time use only:** A Press-In Bottle Adapter (PIBA) is provided with the oral syringe. This is the device that gets inserted into the neck of the bottle to make it easier to withdraw the solution using the oral syringe. If the PIBA is not already in place, remove the PIBA and 5 ml oral syringe from the plastic overwrap. With the bottle on a flat surface, insert the PIBA into the bottle neck while keeping the PIBA's flat surface facing up and pressing on it (Figure 2).



- Push the syringe plunger to the bottom of the barrel of the syringe (toward its tip) to remove excess air. Attach the syringe to the PIBA with a slight twisting motion (Figure 3).
- Invert the bottle (with the syringe attached) and fill the syringe with the liquid by pulling the syringe plunger down to just beyond the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (Figure 4). Remove air bubbles from the syringe by pushing the plunger up to the appropriate graduation mark.
- Return the bottle to an upright position with the syringe still in the PIBA/bottle (Figure 5).
- Remove the syringe from the bottle/PIBA (Figure 6).
- Empty the contents of the syringe directly into mouth by pushing the syringe plunger to the bottom of the syringe barrel (Figure 7).
Note: Steps 4-7 may need to be repeated up to three times to obtain the total dose (Table 1).
[For example, a 150 mg (7.5 ml) dose will require two withdrawals from the bottle to achieve the entire dose. Using the oral syringe, first withdraw 5 ml and empty contents of syringe directly into the mouth, then refill the oral syringe with 2.5 ml and empty the remaining contents into the mouth.]
- Rinse the syringe by drawing water into the syringe and pushing the syringe plunger to the bottom of the syringe barrel, at least three times (Figure 8).
- Replace the cap on the bottle (leaving the PIBA in place in the bottle neck) (Figure 9).

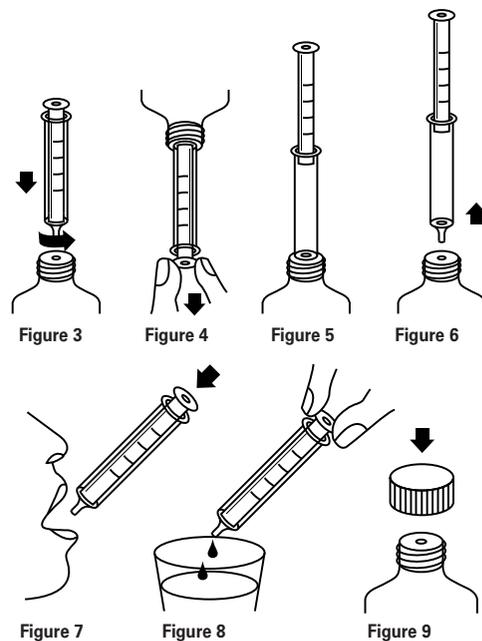


Table 1. Oral Syringe Withdrawals to Deliver Prescribed Dose of Pregabalin Rosemont

Pregabalin Rosemont Dose	Total Solution Volume (ml)	First Syringe Withdrawal (ml)	Second Syringe Withdrawal (ml)	Third Syringe Withdrawal (ml)
25	1.25	1.25	Not required	Not required
50	2.5	2.5	Not required	Not required
75	3.75	3.75	Not required	Not required
100	5	5	Not required	Not required
150	7.5	5	2.5	Not required
200	10	5	5	Not required
225	11.25	5	5	1.25
300	15	5	5	5

If you take more Pregabalin than you should

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

If you forget to take Pregabalin

It is important to take your Pregabalin Rosemont 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

Do not stop taking pregabalin 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, flu-like 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

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

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

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 ('drug dependence').

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

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.

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 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 Rosemont

- Keep 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. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Once opened, the contents of the bottle should be used within 60 days
- 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 Rosemont contains

The active substance is pregabalin. Each ml contains 20 mg pregabalin.

The other ingredients are: methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium dihydrogen phosphate anhydrous, Disodium phosphate, sucralose, strawberry flavouring 10131/P [contains E414 arabic gum, dextrose monohydrate, maltodextrine, flavouring substances regulated by 1334/2008/CE], purified water.

What Pregabalin Rosemont looks like and contents of the pack

Pregabalin Rosemont 20 mg/ml oral solution is a clear colourless solution in a white plastic bottle containing 473 ml of oral solution, in a cardboard carton. The carton also contains a white, plastic 5ml oral syringe with 1.25ml graduations and a white, plastic press-in bottle adapter (PIBA).

The Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

Manufacturer: ONE PHARMA S.A., 60th km New National Road Athinon-Lamias 320 09 Sximatari Voiotias, Greece.

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