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What PEGASET is used for

Pregabalin belongs to a group of medicines called Anti-epileptics. You have been prescribed Pregabalin because:

Pregabalin is used to treat:

Neuropathic pain

Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults.

Epilepsy

Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation.

Generalised Anxiety Disorder

Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.

Fibromyalgia

Pregabalin is indicated for the management of fibromyalgia.

How PEGASET works

Pregabalin helps decrease the number of nerve signals, and as a result calms down overly sensitive nerve cells.

Before you use PEGASET

-When you must not use it

Do not start taking Pregabalin if you are allergic to Pregabalin or any of the Excipients in Pregabalin. See the end of this leaflet for a complete list of Excipients in Pregabalin. Symptoms of an allergic reaction to Pregabalin may include:

- Serious, even life-threatening allergic reactions
- Suicidal thoughts or actions.
- Swelling of your hands, legs and feet.
- Faintness and sleepiness

-Before you start to use it

Tell your healthcare provider about all your medical conditions including if you

- Have or had depression, mood problems or suicidal thoughts or behavior.
- Have kidney problems or get kidney dialysis.
- Have heart problems including heart failure.
- Have a bleeding problem or a low blood platelet count
- Have abused prescription medicines, street drugs, or alcohol in the past.
- Have ever had swelling in your face, mouth, tongue, lips, gums, neck or throat (angioedema).
- Are pregnant or plan to become pregnant. It is not known if will harm your unborn baby. You and your healthcare provider will have to decide if you should take Pregabalin while you are pregnant.
- Are breastfeeding. It is not known if Pregabalin passes into breast milk and if it can harm your baby. You and your healthcare provider should discuss whether you should take Pregabalin or breast-feed, but you should not do both.

-Taking other medicines

Tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins or herbal supplements.

Pregabalin and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take:

- Phenytoin, carbamazepine, valproic acid, lamotrigine, gabapentin, lorazepam, oxycodone or ethanol

How to use PEGASET

-How much to use

The dose range is 150 to 600 mg per day given in either two or three divided doses.

Neuropathic pain

Pregabalin treatment can be started at a dose of 150 mg per day. Based on individual patient response and tolerability, the dosage may be increased to 300 mg per day after an interval of 3 to 7 days, and if needed, to a maximum dose of 600 mg per day after an additional 7-day interval.

Fibromyalgia

The usual dose range for most patients is 300 to 450 mg per day given in two divided doses. Some patients may derive additional benefit at 600 mg per day.

Epilepsy

Pregabalin treatment can be started with a dose of 150 mg per day. Based on individual patient response and tolerability, the dosage may be increased to 300 mg per day after 1 week.

Generalised anxiety disorder

The dose range is 150 to 600 mg per day given as two or three divided doses. The need for treatment should be reassessed regularly.

Patients with renal impairment

Dosage reduction in patients with compromised renal function must be individualised according to creatinine clearance (CL_{cr}).

For patients receiving hemodialysis, the pregabalin daily dose should be adjusted based on renal function. In addition to the daily dose, a supplementary dose should be given immediately following every 4-hour haemodialysis treatment:

Creatinine Clearance (CL _{cr}) (mL/min)	Total Pregabalin Daily Dose*		Dose Regimen
	Starting Dose (mg/day)	Maximum Dose (mg/day)	
≥60	150	600	BID or TID
≥30 - <60	75	300	BID or TID
≥15 - <30	25 - 50	150	QD or BID
<15	25	75	QD
Supplementary dosage following haemodialysis (mg)			
	25	100	Single dose*

TID = Three divided doses.

BID = Two divided doses.

QD = Single daily dose.

*Total daily dose (mg/day) should be divided as indicated by dose regimen to provide mg/dose.

+Supplementary dose is a single additional dose.

Use in patients with hepatic impairment

No dosage adjustment is required for patients with hepatic impairment.

Use in children and adolescents (12 to 17 years of age)

The safety and effectiveness of pregabalin in pediatric patients below the age of 12 years and adolescents has not been established.

The use in children is not recommended.

Use in the elderly (over 65 years of age)

Elderly patients may require a dose reduction of pregabalin due to decreased renal function.

-When to use it

Pregabalin may be taken with or without food.

Take Pregabalin exactly as prescribed. Your healthcare provider will tell you when to take Pregabalin. It is advised to take Pregabalin at the same times each day.

-How long to use it

Do not stop taking Pregabalin without checking with your healthcare provider. If you stop taking Pregabalin suddenly you may have headaches, nausea, diarrhoea or trouble sleeping. If you have epilepsy and you stop taking Pregabalin suddenly, you may have seizures more often. Talk with your healthcare provider about how to stop Pregabalin slowly.

-If you forget to use it

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, just skip the missed dose. Take the next dose at your regular time. Do not take two doses at the same time.

-If you use too much (overdose)

If you take too much Pregabalin, call your healthcare provider or poison control center, or go to the nearest emergency room right away.

While you are using it

-Things you must do

Stop taking Pregabalin and call your healthcare provider immediately if you have any of these signs of a serious allergic reaction: Swelling of your face, mouth, lips, gums, tongue, throat or neck, trouble breathing, rash, hives (raised bumps) or blisters. Call your healthcare provider immediately if you have any of these symptoms, especially if they are new, worse or worry you:

Thoughts about suicide or dying, trouble sleeping (insomnia), attempts to commit suicide, new or worse irritability, new or worse depression, acting aggressive, being angry or violent, new or worse anxiety, acting on dangerous impulses, feeling agitated or restless, an extreme increase in activity and talking (mania), panic attacks, other unusual changes in

behaviour or mood.

-Things you must not do

Do not drive a car, work with machines, or do other dangerous activities until you know how Pregabalin affects you.

Ask your healthcare provider about when it will be okay to do these activities.

Do not drink alcohol while taking Pregabalin. Pregabalin and alcohol can affect each other and increase side effects such as sleepiness and dizziness.

-Things to be careful of

If you have suicidal thoughts or actions, do not stop Pregabalin without first talking to a healthcare provider

- Stopping Pregabalin suddenly can cause serious problems.

- Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviours, thoughts or feelings.

- Keep all follow-up visits with your healthcare provider as scheduled.

- Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Side effects:

Pregabalin may cause serious side effects, including:

- Muscle problems, muscle pain, tenderness, or weakness.

- If you have these symptoms, especially if you feel sick and have a fever, tell your healthcare provider right away. Problems with your eyesight, including blurry vision. Call your healthcare provider if you have any changes in your eyesight.

- Weight gain, if you have diabetes, weight gain may affect the management of your diabetes. Weight gain can also be a serious problem for people with heart problems

- Feeling "high"

- The most common side effects of Pregabalin include:

Nasopharyngitis

Appetite increased

Faintness

Vomiting

Constipation

Euphoric mood

Confusion

Irritability

Disorientation

Insomnia

Trouble concentrating

Blurry vision

Swelling of hands and feet

Weight gain

Dry mouth

Ataxia (loss in control of body movement)

Tremor

Diplopia (double vision)

Sleepiness

Vertigo

If you have diabetes, you should pay attention to your skin while taking Pregabalin and tell your healthcare provider about any sores or skin problems. Tell your healthcare provider about any side effect that bothers you or that does not go away.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of PEGASET

-Storage

Store Pregabalin capsules at room temperature. Do not store above 30°C in its original package.

Safely throw away any Pregabalin that is out of date or no longer needed.

Keep Pregabalin and all medicines out of the reach of children.

-Disposal

Medicines should not be disposed off via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

-What it looks like

PEGASET 50: White cap/ white body,

size '4' hard gelatin capsule shells, imprinting with "Z" on cap and "11" on body with black ink contains white to off- white granular powder.

PEGASET 75: Orange cap/ white body, size '4' hard gelatin capsule shells, imprinting with "Z" on cap and "12" on body with black ink contains white to off- white granular powder.

PEGASET 150: White cap/ White body, size '2' hard gelatin capsule shells, imprinting with "Z" on cap and "14" on body with black ink contains white to off- white granular powder.

-Ingredients

Active ingredient (s): Pregabalin.

Inactive ingredients:

Capsule content

Maize starch

Talc

Capsule Shell

Iron Oxide Red (E 172)

Titanium Dioxide(E171)

Gelatin

Sodium Lauryl sulfate

Capsule printing ink:

Shellac

Black Iron Oxide (E172).

-MAL number:

Pegaset 50: MAL18056154AZ

Pegaset 75: MAL18056155AZ

Pegaset 150: MAL18056156AZ

Manufacturer

Aurobindo Pharma Limited,
Unit XV Plot No 17a, E Bonangi Village,
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Product Registration Holder:

Healol Pharmaceuticals Sdn. Bhd.
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Malaysia.

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