

APO-Pregabalin

Contains the active ingredient pregabalin

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about pregabalin. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Pregabalin. It contains the active ingredient pregabalin.

It is used to:

- treat neuropathic pain, which is pain caused by an abnormality of, or damage to, the nerves
- control epilepsy. Epilepsy is a condition where you have repeated seizures (fits). There are many different types of seizures, ranging from mild to severe.

Pregabalin may be used alone, or in combination with other medicines, to treat your condition.

Your doctor may prescribe pregabalin in addition to your current therapy when your current treatment is no longer working as well as before.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

Pregabalin belongs to a group of medicines called anticonvulsants. These drugs are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

Pregabalin also has analgesic effects (relieves pain).

Use in children

There is not enough information to recommend the use of this medicine in children under the age of 18 years.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- You have had an allergic reaction to pregabalin or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin; fainting or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:

- any other medicines, especially barbiturates or any other anticonvulsant medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - congestive heart failure
 - hereditary problems with galactose metabolism
 - kidney problems
 - diabetes
 - depression
 - a history of substance abuse.
 3. Tell your doctor if you have a history of substance abuse.

There have been reported cases of misuse and abuse with pregabalin.

4. You are currently pregnant or you plan to become pregnant.

Pregabalin is not recommended for use during pregnancy. However, if you have epilepsy, it is very important to control your fits while you are pregnant. If it is necessary for you to take pregabalin, your doctor can help you decide whether or not to take it during pregnancy.

5. You are currently breast-feeding or you plan to breast-feed.

It is recommended that you do not breast-feed while taking pregabalin, as it passes into breast milk and its safety in infants is unknown.
6. You are planning to have surgery or an anaesthetic.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with pregabalin. These include:

- oxycodone, morphine or codeine, pain relievers called opioid analgesics

- lorazepam, a medicine used to treat anxiety
- medicines used to treat allergies (antihistamines)
- medicines used to treat certain psychiatric disorders.

Taking these medicines together with pregabalin may increase your chance of experiencing side effects. You may need a different dose or need to take different medicines. Your doctor or pharmacist will advise you.

Other medicines not listed above may also interact with pregabalin.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your age, your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

Your doctor may recommend that you start with a low dose of pregabalin and slowly increase the dose to the lowest amount needed to control your epilepsy/convulsions or neuropathic pain.

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

How to take it

Swallow the capsules whole with a full glass of water.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and

will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine, even if you feel well.

Do not stop taking pregabalin, or lower the dosage, without checking with your doctor.

If you stop taking pregabalin suddenly you may worsen your condition or cause unwanted effects such as sleeplessness, headache, nausea (feeling sick), anxiety, excessive sweating or diarrhoea (runny stools). If appropriate, your doctor will slowly reduce your dose before you can stop taking it completely.

Make sure you have enough pregabalin to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose (within 4 hours), skip the missed dose and take your next dose at the usual time.

Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose with pregabalin may include mood changes, feeling tired, confusion, depression, agitation and restlessness or seizures.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital. Pregabalin may affect other medicines used during surgery.
- you experience any changes in your vision. Pregabalin may cause blurring or other changes in eyesight. Your doctor may ask you to stop taking pregabalin to improve these symptoms.
- you have any thoughts of suicide or self-harm, any unusual changes in mood or behaviour, or show signs of depression

Some people being treated with anti-epileptics such as pregabalin have had thoughts of harming themselves or taking their life.

Patients and caregivers should be alert and monitor for these effects.

Signs and symptoms of suicidal risk include:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- new or an increase in aggressive behaviour, irritability or agitation
- new or worsening depression.

Mention of suicide or violence must be taken seriously.

If you or someone you know is demonstrating these warning signs of suicide while taking pregabalin, contact your doctor or a mental health professional right away.

Tell your doctor if:

- you feel that pregabalin is not helping your condition. Your doctor may need to change your medicine.
- you have not taken pregabalin exactly as prescribed. Your doctor otherwise may change your treatment unnecessarily.

If you become pregnant while taking pregabalin, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

As with other anticonvulsant medicines, pregabalin may cause dizziness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, symptoms such as dizziness and drowsiness may be worse.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking pregabalin or if you have any questions or concerns.

Pregabalin helps most people with neuropathic pain or epilepsy, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

It can be difficult to tell whether side effects are the result of taking pregabalin, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

If you are over 65 years of age you may have an increased chance of getting side effects.

If you get any side effects, do not stop taking pregabalin without first talking to your doctor.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor if you notice any of the following:

- dizziness
- feeling tired or drowsy
- constipation
- diarrhoea
- nausea
- headache
- increase in weight
- unsteadiness when walking, reduced co-ordination, shaking or tremors
- dry mouth
- blurred or double vision.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects. You may need medical attention.

- unusual changes in mood or behaviour
- signs of new or increased irritability or agitation
- signs of depression
- swelling of the hands, ankles or feet
- enlargement of breasts
- unexplained muscle pain, tenderness and weakness
- passing little to no urine.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

- shortness of breath, swelling of the feet and legs, weight increase due to fluid build-up
- irritated red eyes that are sensitive to light

- more frequent or more severe seizures (fits)
- sudden signs of allergy such as rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some patients. Some of these side effects (for example, changes in blood pressure) can only be found when your doctor does tests from time to time to check your progress.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Pregabalin looks like

25 mg capsules: white body/white cap, imprinted with "APO" and "P25" in black ink.

50 mg capsules: white body/white cap, imprinted with "APO" and "P50" in black ink.

75 mg capsules: white body/orange cap, imprinted with "APO" and "P75" in black ink.

100 mg capsules: orange body/orange cap, imprinted with "APO" and "P100" in black ink.

150 mg capsules: white body/white cap, imprinted with "APO" and "P150" in black ink.

200 mg capsules: light orange body/light orange cap, imprinted with "APO" and "P200" in black ink.

225 mg capsules: white body/light orange cap, imprinted with "APO" and "P225" in black ink.

300 mg capsules: white body/orange cap, imprinted with "APO" and "P300" in black ink.

Available in blister packs of 14, 20, 56 and 60 tablets.

Also available in bottles of 14, 20, 56 and 60 tablets.

Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each capsule contains 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg,

225 mg or 300 mg of pregabalin as the active ingredient.

It also contains the following inactive ingredients:

- lactose monohydrate
- purified talc
- maize starch
- gelatin
- purified water
- titanium dioxide
- sodium lauryl sulfate

- TekPrint SW-9008 black ink
- iron oxide red (75 mg, 100 mg, 200 mg, 225 mg or 300 mg strengths only).

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

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Australian Registration Numbers

APO-Pregabalin 25 mg capsules
(bottle): AUST R 193211

APO-Pregabalin 50 mg capsules
(bottle): AUST R 193246

APO-Pregabalin 75 mg capsules
(bottle): AUST R 193247

APO-Pregabalin 100 mg capsules
(bottle): AUST R 193248

APO-Pregabalin 150 mg capsules
(bottle): AUST R 193249

APO-Pregabalin 200 mg capsules
(bottle): AUST R 193252

APO-Pregabalin 225 mg capsules
(bottle): AUST R 193253

APO-Pregabalin 300 mg capsules
(bottle): AUST R 193254

APO-Pregabalin 25 mg capsules
(blister pack): AUST R 193255

APO-Pregabalin 50 mg capsules
(blister pack): AUST R 193256

APO-Pregabalin 75 mg capsules
(blister pack): AUST R 193274

APO-Pregabalin 100 mg capsules
(blister pack): AUST R 193275

APO-Pregabalin 150 mg capsules
(blister pack): AUST R 193276

APO-Pregabalin 200 mg capsules
(blister pack): AUST R 193277

APO-Pregabalin 225 mg capsules
(blister pack): AUST R 193278

APO-Pregabalin 300 mg capsules
(blister pack): AUST R 193279

Sponsor

Apotex Pty Ltd

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