

PREGABALIN APOTEX

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

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

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

PREGABALIN APOTEX is also used to 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 APOTEX belongs to a group of medicines called anticonvulsants.

These medicines are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

PREGABALIN APOTEX also has pain relieving effects.

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

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

Your doctor, however, may use PREGABALIN APOTEX for another purpose.

Ask your doctor if you have any questions about why it has been given to you.

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

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 an allergy to:

- any medicine containing pregabalin
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

- any other medicines, especially barbiturates or any other anticonvulsant medicine
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

PREGABALIN APOTEX is not recommended to be used 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 APOTEX, your doctor can help you decide whether or not to take it during pregnancy.

Tell your doctor or pharmacist if you are breastfeeding or planning to breastfeed.

It is recommended that you do not breast-feed while taking PREGABALIN APOTEX, as it is not known whether it passes into breast milk.

Tell your doctor if you have or have had any of the following medical conditions:

- congestive heart failure
- hereditary problems with galactose metabolism
- kidney problems
- diabetes
- a history of substance abuse
- depression

Tell your doctor or pharmacist if you have a history of substance abuse.

There have been reported cases of misuse and abuse with PREGABALIN APOTEX.

If you have not told your doctor about any of the above, tell him/her before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by PREGABALIN APOTEX, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you. 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.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking PREGABALIN APOTEX.

How to take this medicine

How much to take

The dose varies from patient to patient.

Your doctor will tell you how many capsules you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.

Your doctor may recommend that you start with a low dose of PREGABALIN APOTEX 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 your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

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 APOTEX, or lower the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

Stopping PREGABALIN APOTEX suddenly 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.

If you forget to take it

If it is almost time for your next dose (within 4 hours), skip the dose you missed and take your next dose when you are meant to.

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 the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose with PREGABALIN APOTEX may include mood changes, feeling tired, confusion, depression, agitation and restlessness.

While you are using this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Tell your doctor immediately if you experience any changes in your vision.

PREGABALIN APOTEX may cause blurring or other changes in eyesight. Your doctor may ask you to stop taking PREGABALIN APOTEX to improve these symptoms.

Tell your doctor immediately if 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 APOTEX 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 APOTEX, contact your doctor or a mental health professional right away.

Tell your doctor if you feel PREGABALIN APOTEX is not helping your condition.

Your doctor may need to change your medicine.

Tell your doctor if, for any reason, you have not taken PREGABALIN APOTEX exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily.

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

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

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

Things to be careful of

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

As with other anticonvulsant medicines, PREGABALIN APOTEX 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

PREGABALIN APOTEX 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, most of the time they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking PREGABALIN APOTEX, 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.

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

If you get any side effects, do not stop taking PREGABALIN APOTEX without first talking to your doctor or pharmacist. Ask your doctor or pharmacist to answer any questions you may have.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- 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.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

Other side effects not listed above may also 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. Tell your doctor if you notice anything that is making you feel unwell.

Storage and Presentation

Storage

Keep your capsules in the pack/bottle until it is time to take them.

If you take the capsules out of the pack/bottle they may not keep well.

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

Do not store this 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 it 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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

PREGABALIN APOTEX 25 mg:

- Light grey cap and body hard gelatin capsule with imprinting symbol "25"

PREGABALIN APOTEX 75 mg:

- Light red cap and light grey body hard gelatin capsule with imprinting symbol "75"

PREGABALIN APOTEX 150 mg:

- Light grey cap and body hard gelatin capsule with imprinting symbol "150"

PREGABALIN APOTEX 300 mg:

- Red cap and body light grey hard gelatin capsule with imprinting symbol "300".

Available in PVC/Al blister packs of 56 capsules.

Ingredients

The active ingredient in PREGABALIN APOTEX is pregabalin.

This medicine also contains the following:

- lactose
- starch – pregelatinised maize
- talc - purified
- gelatin
- titanium dioxide
- iron oxide black
- iron oxide red (75 mg and 300 mg capsules only)
- iron oxide yellow (75 mg and 300 mg capsules only).

Australian registration numbers

25 mg capsules - AUST R 267552

75 mg capsules - AUST R 267554

150 mg capsules - AUST R 267556

300 mg capsules - AUST R 267559

Supplier

Southern Cross Pharma Pty Ltd

Suite 5/118 Church Street

Hawthorn VIC 3122

Australia

Distributor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

Australia

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