

# APO-Pregabalin

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

### 1. Why am I taking APO-Pregabalin?

APO-Pregabalin contains the active ingredient, pregabalin. APO-Pregabalin is taken to treat neuropathic pain, which is pain caused by an abnormality of, or damage to, the nerves.

For more information, see Section [1. Why am I taking APO-Pregabalin?](#) in the full CMI.

### 2. What should I know before I use APO-Pregabalin?

Do not take if you have ever had an allergic reaction to APO-Pregabalin or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines (including benzodiazepines and opioids), or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take APO-Pregabalin?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with APO-Pregabalin and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take APO-Pregabalin?

- APO-Pregabalin should be administered once daily after an evening meal. It should be swallowed whole and should not be split, ushed or chewed.

More instructions can be found in Section [4. How do I take APO-Pregabalin?](#) in the full CMI.

### 5. What should I know while taking APO-Pregabalin?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking APO-Pregabalin</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking this medicine suddenly</li><li>• It is recommended to withdraw it gradually over a minimum of one week</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• APO-Pregabalin may cause dizziness and drowsiness in some people</li><li>• If you experience any of these symptoms, do not drive, operate machinery or do not do anything else that could be dangerous</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• If you drink alcohol, symptoms such as dizziness and drowsiness may be worsen</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• APO-Pregabalin should be stored below 25°C</li></ul>

For more information, see Section [5. What should I know while taking APO-Pregabalin?](#) in the full CMI.

### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. **Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Some common, less serious side effects include dizziness, feeling tired or drowsy, headache, unsteadiness when walking, reduced coordination, shaking or tremors, constipation, diarrhoea, nausea, dry mouth, blurred or double vision, abdominal pain, and increase in weight. Serious side effects include unusual changes in mood or behaviour, increased irritability, anxiety or depression, thoughts of suicide, swelling of the face, lips, tongue, hands, ankles or feet, unexplained muscle pain, tenderness and weakness, irritated red eyes that are sensitive to light, and shortness of breath, wheezing or difficulty breathing.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

**WARNING:**

**APO-PREGABALIN as an add-on therapy for adults with partial onset seizures has not been established. APO-PREGABALIN should be gradually decreased over a minimum period of 1 week to avoid seizures.**

**Before taking APO-Pregabalin, tell your doctor if you have a history of drug abuse. APO-Pregabalin poses risks of misuse, abuse and dependence. Using APO-Pregabalin with other medicines that can make you feel drowsy such as sleeping tablets and other pain relievers (e.g. benzodiazepines and opioids), antihistamines, antidepressants, antipsychotics, cannabis, and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. If you have any concern about taking this medicine, speak to your doctor.**

# APO-Pregabalin

Active ingredient: *pregabalin (PRE-gab-a-lin)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking APO-Pregabalin. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking APO-Pregabalin.**

**Where to find information in this leaflet:**

- [1. Why am I taking APO-Pregabalin?](#)
- [2. What should I know before I take APO-Pregabalin?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take APO-Pregabalin?](#)
- [5. What should I know while taking APO-Pregabalin?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking APO-Pregabalin?

**APO-Pregabalin contains the active ingredient, pregabalin.**

APO-Pregabalin belongs to a group of medicines called anticonvulsants and has pain relieving effects.

**APO-Pregabalin is taken to treat neuropathic pain, which is pain caused by an abnormality of, or damage to, the nerves.**

## 2. What should I know before I take APO-Pregabalin?

### Warnings

**Do not take APO-Pregabalin if:**

- you are allergic to pregabalin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can take this medicine.
- 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.
  - reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes.

**Check with your doctor if you:**

- have any other medical conditions such as:
  - congestive heart failure,
  - hereditary problems with galactose metabolism,
  - kidney problems,
  - diabetes,
  - depression.
- take any medicines for any other condition.
- **have a history of drug abuse.**

APO-Pregabalin poses risks of abuse, misuse and dependence. Your body may become used to you taking APO-Pregabalin and this may result in physical dependence. It means that you may experience withdrawal symptoms if you stop taking APO-Pregabalin suddenly. So it is important to strictly follow the directions given by your doctor.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

APO-Pregabalin is not recommended for use during pregnancy.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The active ingredient in APO-Pregabalin passes into breast milk and its safety in infants is unknown. It is recommended that you do not breastfeed while taking APO-Pregabalin.

### Use in children

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

### 3. What if I am taking other medicines?

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

APO-Pregabalin and certain other medicines may influence each other (interaction). **Using APO-Pregabalin with other medicines that**

**can make you feel drowsy, such as sleeping tablets and other pain relievers (e.g. benzodiazepines and opioids), antihistamines, antidepressants, antipsychotics, cannabis, and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death.** Your doctor will minimize the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation.

You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-Pregabalin .**

### 4. How do I take APO-Pregabalin?

#### How much to take

- Take APO-Pregabalin exactly as prescribed. Your doctor will tell you how much APO-Pregabalin to take.
- Your doctor may recommend that you start with a low dose of APO-Pregabalin and slowly increase the dose to the lowest amount needed to control your epilepsy/ convulsions or neuropathic pain.
- Follow the instructions provided and take APO-Pregabalin until your doctor tells you to stop.
- Take APO-Pregabalin once a day, after an evening meal. Your medicine may not be as effective if taken on an empty stomach.

#### When to take APO-Pregabalin

- APO-Pregabalin must be taken once daily after an evening meal. The tablet should be swallowed whole and should not be split, crushed or chewed. Always take your medicine as directed by your doctor.

#### If you forget to take APO-Pregabalin

APO-Pregabalin must be taken once daily after an evening meal.

If you miss your dose at the usual time, take it prior to bedtime following a snack.

If you miss the dose prior to bedtime, then take it following your morning meal.

If you do not take the dose the following morning, then take the next dose at your regular time after your evening meal.

**Do not take a double dose to make up for the dose you missed.**

#### If you take too much APO-Pregabalin

If you think that you have taken too much APO-Pregabalin, you may need urgent medical attention.

Symptoms of an overdose with APO-Pregabalin may include mood changes, feeling tired, confusion, depression, agitation,

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while taking APO-Pregabalin?**

### **Things you should do**

Remind any doctor, dentist or pharmacist you visit that you are taking APO-Pregabalin.

If you have nervous system or respiratory disorders, kidney problems, or you are older than 65, your doctor may adjust your dose.

If you are going to have surgery, tell your surgeon and anaesthetist that you are taking APO-Pregabalin as it may affect other medicines taken during the procedure.

### **Call your doctor straight away if you:**

- experience any hypersensitivity reactions (such as skin redness, hives, rash, reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes): Discontinue APO-Pregabalin and immediately seek medical care.
- experience any changes in vision: APO-Pregabalin may cause blurring or other changes in eyesight.
- have any thoughts of suicide or self-harm, any unusual changes in mood or behavior, or show signs of depression.
- experience trouble breathing or shallow breaths.
- become pregnant while taking APO-Pregabalin.
- feel that APO-Pregabalin is not helping your condition.

Continue APO-Pregabalin 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.

### **Things you should not do**

- Do not stop taking this medicine or lower the dosage without checking with your doctor.
- Do not let yourself run out of medicine over the weekend or on holidays.

Stopping APO-Pregabalin suddenly may worsen your condition or increase your chance of experiencing withdrawal symptoms, 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.

- Do not take APO-Pregabalin to treat any other symptoms unless your doctor tells you so.
- Do not give APO-Pregabalin to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.

## Driving or using machines

**Be careful before you drive or use any machines or tools until you know how APO-Pregabalin affects you.**

APO-Pregabalin may cause dizziness and drowsiness in some people. If you experience any of these symptoms, do not drive, operate machinery or do not do anything else that could be dangerous.

## Drinking alcohol

**Tell your doctor if you drink alcohol.**

Alcohol may interfere with APO-Pregabalin and increase side effects such as sleepiness and dizziness.

## Looking after your medicine

- Store below 25°C.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Nervous system related</b> <ul style="list-style-type: none"><li>• dizziness</li><li>• feeling tired or drowsy</li><li>• headache</li><li>• unsteadiness when walking, reduced coordination, shaking or tremors</li></ul> <b>Gastrointestinal related</b> <ul style="list-style-type: none"><li>• abdominal pain</li><li>• constipation</li><li>• diarrhoea</li><li>• nausea</li><li>• dry mouth</li></ul> <b>Eye related</b> <ul style="list-style-type: none"><li>• blurred or double vision</li></ul> <b>Body related</b> <ul style="list-style-type: none"><li>• increase in weight</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<b>Nervous system related</b> <ul style="list-style-type: none"><li>• unusual changes in mood or behaviour</li><li>• extreme increase in activity and talking (mania)</li><li>• acting aggressive, being angry, or violent</li><li>• panic attacks</li><li>• signs of</li><li>• irritability, agitation, or restlessness</li><li>• signs of new or worse anxiety</li><li>• signs of new or worse depression</li><li>• thoughts about suicide or dying</li><li>• attempts to commit suicide</li><li>• acting on dangerous impulses</li><li>• trouble sleeping (insomnia)</li><li>• confusion</li></ul> <b>General effect</b> <ul style="list-style-type: none"><li>• swelling of the face, lips, tongue, hands, ankles or feet</li><li>• enlargement of breasts</li><li>• passing little to no urine</li></ul> <b>Musculoskeletal related</b> <ul style="list-style-type: none"><li>• unexplained muscle pain, tenderness and weakness</li><li>• weight increase due to fluid build-up</li><li>• swelling of the feet and legs</li></ul> <b>Eye related</b> <ul style="list-style-type: none"><li>• irritated red eyes that are sensitive to light</li></ul> <b>Respiratory related</b> <ul style="list-style-type: none"><li>• shortness of breath, wheezing or difficulty breathing</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What APO-Pregabalin contains

<b>Active ingredient</b>	25 mg capsules - 25 mg pregabalin
<b>(main ingredient)</b>	75 mg capsules - 75 mg pregabalin

	150 mg capsules - 150 mg pregabalin 300 mg capsules - 300 mg pregabalin
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• Pregelatinised maize starch</li> <li>• Purified talc</li> <li>• Gelatin</li> <li>• Sodium lauryl sulfate</li> <li>• Titanium dioxide</li> <li>• Iron oxide red (75 mg and 300 mg capsules only)</li> </ul>
<b>Potential allergens</b>	May contain traces of sulfites.

**Do not take this medicine if you are allergic to any of these ingredients.**

### ***What APO-Pregabalin looks like***

25 mg –

white hard gelatin capsule, marked 'S' on the cap and '466' on the body with black ink.

**blister pack:** AUST R 308067, **bottle:** AUST R 308082

75 mg - white and orange hard gelatin capsule, marked 'S' on the cap and '468' on the body with black ink

**blister pack:** AUST R 308104, **bottle:** AUST R 308080

150 mg - White colored cap and White colored body, printed as "S" in Cap and "470" in body with black ink

**blister pack:** AUST R 308093, **bottle:** AUST R 308076

300 mg - Orange colored cap and White colored body, printed as "S" in Cap and "473" in body with black ink

**blister pack:** AUST R 308086, **bottle:** AUST R 308100

*Bottle presentations not marketed in Australia*

### ***Who distributes APO-Pregabalin***

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel Street

Cremorne VIC 3121

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