

# APX-GABAPENTIN capsules

## 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.

**WARNING:** Important safety information is provided in a boxed warning in the [full CMI](#). Read before taking this medicine.

### 1. Why am I using APX-GABAPENTIN?

APX-GABAPENTIN capsules contains the active ingredient gabapentin. APX-GABAPENTIN is used to control epilepsy and treat neuropathic pain. For more information, see Section [1. Why am I taking APX-GABAPENTIN?](#) in the full CMI.

### 2. What should I know before I take APX-GABAPENTIN?

Do not use if you have ever had an allergic reaction to gabapentin 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, or are pregnant or plan to become pregnant or are breastfeeding.**

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

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

Some medicines may interfere with APX-GABAPENTIN 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 APX-GABAPENTIN?

- Your doctor will tell you how many APX-GABAPENTIN 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.
- Swallow APX-GABAPENTIN whole with a full glass of water.

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

### 5. What should I know while taking APX-GABAPENTIN?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist, surgeon, or anaesthetist you visit that you are taking APX-GABAPENTIN.</li><li>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.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not stop taking APX-GABAPENTIN or lower the dose without checking with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Do not drive, operate machinery, ride a bike as APX-GABAPENTIN may cause drowsiness, dizziness, lightheadedness or sleepiness in some people.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>Avoid alcohol as it can make you more sleepy, dizzy or light-headed.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep your capsules in a cool dry place where the temperature stays below 25°C</li></ul>

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

### 6. Are there any side effects?

Common side effects include dizziness, light-headedness, headache, sleeplessness, feeling tired, drowsy, unfriendliness, unusually overactive, forgetfulness, loss of concentration, confusion, difficulty speaking, weight change, constipation, diarrhoea, nausea, vomiting, indigestion, dry mouth, red swollen gums, muscle pain, cramps, back pain, swelling hand or feet, runny or blocked nose, fever, bronchitis, lung infection, sore throat, coughing. Serious side effects include unusual changes in mood or behaviour, increased irritability or agitation, depression, seeing or hearing things that are not there, blurred or double vision, uncontrollable jerky eye movements, difficulty seeing, fever, severe chills, sore throat or mouth ulcers, trouble breathing, loss of consciousness, severe seizures, chest pain, fast heart rate, sudden signs of allergy, severe skin rash, high body temperature enlarged lymph nodes 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:** Before taking APX-GABAPENTIN, tell your doctor if you have a history of drug abuse. APX-GABAPENTIN poses risks of abuse and dependence. Taking APX-GABAPENTIN 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.

# APX-GABAPENTIN capsules

Active ingredient(s): *gabapentin*

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking APX-GABAPENTIN. **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 APX-GABAPENTIN.**

Where to find information in this leaflet:

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

## 1. Why am I taking APX-GABAPENTIN?

APX-GABAPENTIN contains the active ingredient *gabapentin*.

APX-GABAPENTIN belongs to a group of medicines called anticonvulsants.

**APX-GABAPENTIN is 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.**

**APX-GABAPENTIN is also used to treat neuropathic pain, type of pain caused by damage to the nerves.**

This medicine is thought to work by controlling brain chemicals which send signals to nerves to help control seizures or neuropathic pain.

APX-GABAPENTIN also has pain relieving effects.

Your doctor may have prescribed APX-GABAPENTIN in addition to other medicines that you may be taking. This may be necessary if your current treatment is no longer working as well.

Your doctor may have prescribed APX-GABAPENTIN for another reason.

APX-GABAPENTIN may lead to dependence on this medicine.

Ask your doctor if you have any questions about why APX-GABAPENTIN has been prescribed for you.

## Use in children

There is not enough information to recommend the use of this medicine in children:

- under the age of 3 years to control epilepsy, or
- under the age of 18 years to treat neuropathic pain

## 2. What should I know before I take APX-GABAPENTIN?

### Warnings

**When you must not take APX-GABAPENTIN**

**Do not take APX-GABAPENTIN if:**

- you are allergic to gabapentin, or 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.
- Always check the ingredients to make sure you can take this medicine.
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

**Check with your doctor if you:**

- have allergies to any other medicines, especially barbiturates or any other anticonvulsant medicines or any other substances, such as foods, preservatives or dyes.
- have any other medical conditions:
  - kidney problems
  - mixed seizure disorders that include absence seizures.
- take any medicines for any other condition
- have a history of drug abuse and/or psychiatric disorders.
  - APX-GABAPENTIN poses risks of abuse and dependence. Your body may become used to you taking APX-GABAPENTIN and this may result in physical dependence. It means that you may experience withdrawal symptoms if you stop taking APX-GABAPENTIN suddenly. So it is important to strictly follow the directions given by your doctor.
- are pregnant or plan to become pregnant.

- are breast-feeding or plan to breast-feed.
- if you notice any of the symptoms related to these serious skin reactions described in section 6 under table titled "Serious side effects", stop taking gabapentin and seek medical attention immediately.
  - Serious skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with gabapentin.

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

### Pregnancy

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

If you are pregnant or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the medicine you are taking might pose to your unborn baby.

If you are planning to become pregnant you should discuss your treatment with your doctor as early as possible before you become pregnant. Effective contraception must be used by women of childbearing potential.

APX-GABAPENTIN should not be taken during pregnancy, unless you are told otherwise by your doctor. APX-GABAPENTIN may affect your developing baby if you take it during pregnancy. Some medicines used to treat epilepsy have reported an increased risk of harm to the developing baby.

You should not stop your treatment without discussing this with your doctor.

Do not suddenly discontinue taking this medicine. If taken during pregnancy, gabapentin may lead to withdrawal symptoms in newborn infants. This risk might be increased when gabapentin is taken together with opioid analgesics (medicines for treatment of severe pain).

It is also very important to control your fits while you are pregnant. If it is necessary for you to take APX-GABAPENTIN, your doctor can help you decide whether or not to take it during pregnancy.

### Breastfeeding

Gabapentin, the active substance of APX-GABAPENTIN, is passed on through breast milk. Because the effect on the baby is unknown, tell your doctor if you are breastfeeding or intend to breastfeed.

#### If you do breast-feed, watch your baby carefully.

If your baby develops a skin rash, becomes sleepy or has unusual symptoms, don't breast-feed again until you speak to your doctor.

Your doctor can discuss the risks and benefits of breast-feeding with you.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking APX-GABAPENTIN.

## 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.

### Some medicines may interfere with APX-GABAPENTIN and affect how it works.

Some medicines be affected by APX-GABAPENTIN 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 or pharmacist will advise you accordingly.

APX-GABAPENTIN and certain other medicines may influence each other.

**Taking APX-GABAPENTIN 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 minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation.

Tell your doctor or pharmacist if you are taking any of the following:

- cimetidine, a medicine used to treat stomach or duodenal ulcers
- antacids, medicines used to treat heartburn or reflux
- opioids, medicines used to treat severe pain e.g. morphine.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APX-GABAPENTIN.** Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking APX-GABAPENTIN.

## 4. How do I take APX-GABAPENTIN?

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the pack ask your doctor or pharmacist for help.**

### How much to take

- 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 APX-GABAPENTIN and slowly increase the dose to the lowest amount needed to control your epilepsy/convulsions or neuropathic pain.

- Follow the instructions provided and take APX-GABAPENTIN until your doctor tells you to stop.

### How to take APX-GABAPENTIN

- Swallow APX-GABAPENTIN whole with a full glass of water.

### When to take APX-GABAPENTIN

- **APX-GABAPENTIN should be used at about the same time each day.**
- Taking APX-GABAPENTIN at the same time each day will have the best effect. It will also help you remember when to take the capsules.
- If you are taking APX-GABAPENTIN three times a day, do not allow more than 12 hours between doses.
- It does not matter if you take APX-GABAPENTIN before or after food.

### How long to take APX-GABAPENTIN

- **Continue taking your medicine for as long as your doctor tells you to.**
- APX-GABAPENTIN helps control your condition but does not cure it. Therefore, you must take your medicine every day, even if you feel well.
- **Do not stop taking APX-GABAPENTIN, or lower the dose, without checking with your doctor. Do not let yourself run out of medicine over the weekend or holidays.**
- Stopping APX-GABAPENTIN suddenly may worsen your condition or increase your chance of experiencing withdrawal symptoms, such as anxiety, difficulty sleeping, feeling sick (nausea), pain, excessive sweating, shaking, headache, depression, feeling generally unwell, and diarrhoea (runny stools). These effects usually occur within 48 hours after stopping APX-GABAPENTIN. If you experience withdrawal effects, you should contact your doctor. If you want to stop taking GABAPENTIN-ARX, discuss with your doctor first. They will tell you how to do this. If appropriate, your doctor will slowly reduce your dose before you can stop taking it completely.

### If you forget to take APX-GABAPENTIN

APX-GABAPENTIN should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking APX-GABAPENTIN as you would normally.

**Otherwise 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.**

**Do not take a double dose to make up for the dose 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 APX-GABAPENTIN, ask your pharmacist for help.

### If you take too much APX-GABAPENTIN

If you think that you have used too much APX-GABAPENTIN, you may need urgent medical attention.

**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.**

You may need urgent medical attention.

Symptoms of an overdose may include you falling unconscious feeling drowsy, weak, unsteady when walking, having double vision, slurred speech or diarrhoea.

## 5. What should I know while taking APX-GABAPENTIN?

### Things you must do

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

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking APX-GABAPENTIN.**

**If you are going to have surgery, or emergency treatment, tell the surgeon or anaesthetist that you are taking APX-GABAPENTIN.**

**If you feel APX-GABAPENTIN is not helping your condition, tell your doctor.** Your doctor may need to change your medicine.

**If, for any reason, you have not taken APX-GABAPENTIN exactly as prescribed, tell your doctor.** Otherwise, your doctor may change your treatment unnecessarily.

**If you need to have any medical tests while you are taking APX-GABAPENTIN, tell your doctor.** It may interfere with the results of some tests.

### Call your doctor straight away 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 APX-GABAPENTIN, have had thoughts of harming or killing themselves.

Patients and caregivers should be alert and monitor for signs and symptoms of suicide, these include:

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

o new onset of or worsening of depression.

**Any mention of suicide or violence must be taken seriously.**

- **you or someone you know is demonstrating these warning signs and symptoms of suicide while taking APX-GABAPENTIN, contact your doctor or a mental health professional right away.**
- **you become pregnant while taking APX-GABAPENTIN.**

Remind any doctor, dentist or pharmacist, surgeon you visit that you are taking APX-GABAPENTIN if you are going to have any surgery or procedure (including dental surgery).

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

Your doctor will check your progress and may want to take some tests from time to time. This helps to prevent unwanted side effects.

### Things you must not do

- **Do not take APX-GABAPENTIN to treat any other complaints unless your doctor tells you to.**
- **Do not give APX-GABAPENTIN to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.**
- **Do not stop taking APX-GABAPENTIN or lower the dose without checking with your doctor.**

Stopping APX-GABAPENTIN suddenly, if you have epilepsy, may cause unwanted side effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

### Driving or using machines

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

As with other anticonvulsant medicines, APX-GABAPENTIN may cause drowsiness, dizziness, light-headedness or sleepiness in some people. Make sure you know how you react to APX-GABAPENTIN before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

**Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or sleepy.**

### Drinking alcohol

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

Be careful when drinking alcohol while you are taking APX-GABAPENTIN.

Combining APX-GABAPENTIN and alcohol can make you more sleepy, dizzy or light-headed. Your doctor may suggest you avoid alcohol while you are being treated with APX-GABAPENTIN.

### Looking after your medicine

- Store below 25°C.
- Keep your capsules in the pack until it is time to take them. If you take the capsules out of the pack, they may not keep well.

Follow the instructions in 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.**

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

### Getting rid of any unwanted medicine

If you no longer need to take this medicine, your doctor or pharmacist tells you to stop taking, it is out of date or damaged, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

## 6. Are there any side effects?

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APX-GABAPENTIN.**

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.

It can be difficult to tell whether side effects are the result of taking APX-GABAPENTIN; 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.

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

**If you get any side effects, do not stop taking APX-GABAPENTIN without first talking to your doctor or pharmacist.**

### Less serious side effects

The below list includes the more common side effects of APX-GABAPENTIN. They are usually mild and short-lived

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• dizziness* or light-headedness</li><li>• headache</li><li>• sleeplessness</li><li>• feeling tired or drowsy*</li><li>• unfriendliness*</li><li>• unusually overactive*</li><li>• forgetfulness, loss of concentration or confusion</li><li>• difficulty speaking</li><li>• changes in your weight*</li><li>• constipation, diarrhoea</li><li>• nausea and/or vomiting*, indigestion</li><li>• dry mouth, red swollen gums</li><li>• muscle pain or cramps, back pain</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<ul style="list-style-type: none"> <li>• swelling of the hands of feet</li> <li>• runny or blocked nose</li> <li>• fever*</li> <li>• bronchitis*, lung infection*</li> <li>• sore throat and discomfort when swallowing, coughing.</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• weakness, unsteadiness when walking including falling, reduced co-ordination or slowed reactions (tremor)</li> <li>• unusual changes in mood* or behaviour such as restlessness, nervousness, or excitement</li> <li>• signs of new onset of, or increased irritability or agitation</li> <li>• signs of depression</li> <li>• seeing or hearing things that are not there, irrational thinking</li> <li>• blurred or double vision, uncontrollable jerky eye movements, difficulty seeing</li> <li>• signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> <li>• trouble breathing or shallow breaths (respiratory depression)</li> <li>• loss of consciousness</li> </ul>	<p><b>Tell your doctor as soon as possible and seek medical attention immediately if you notice any of the serious side effects.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• 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. These serious skin rashes can be preceded by fever and flulike symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).</li> <li>• widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).</li> </ul>	<p><b>Tell your doctor as soon as possible and seek medical attention immediately if you notice any of the serious side effects.</b></p>

The side effects in the above lists marked \* have been specifically reported in children taking APX-GABAPENTIN.

### Very Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• more frequent or more severe seizures (fits)</li> <li>• chest pain, a very fast heart rate</li> <li>• sudden signs of allergy such</li> </ul>	<p><b>Call your doctor straight away, or go straight to the</b></p>

<p>as rash, itching or hives, fever, swollen lymph glands, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing.</p>	<p><b>Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> <p>This list includes very serious side effects. You may need urgent medical attention of hospitalisation. These side effects are very rare.</p>
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### 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.

Some of these side effects (for example, changes in thyroid function, structures of bones, high cholesterol, levels of sugar in your blood or blood pressure) can only be found when your doctor does blood tests from time to time to check your progress.

Do not be alarmed by the list of possible side effects. You may not experience any of them.

### 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 APX-GABAPENTIN contains

Active ingredient (main ingredient)	APX-GABAPENTIN contain either 100 mg, 300 mg and 400 mg of gabapentin.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> <li>• lactose monohydrate</li> <li>• purified talc</li> <li>• maize starch</li> <li>• gelatin</li> <li>• titanium dioxide</li> <li>• iron oxide yellow (300 mg and 400 mg capsules only)</li> <li>• iron oxide red (400 mg capsule only)</li> </ul>

	<ul style="list-style-type: none"><li>• TekPrint SB-6018 Blue ink</li></ul>
<b>Potential allergens</b>	Contains sugars as lactose. May contain trace amounts of phenylalanine and sulfites.

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

### **What APX-GABAPENTIN capsule looks like**

APX-GABAPENTIN 100 mg capsules - white capsule printed with "G 100" in blue ink containing a white crystalline powder. (AUST R 335737).

APX-GABAPENTIN 300 mg capsules - yellow capsule printed with "G 300" in blue ink containing a white crystalline powder. (AUST R 335738).

APX-GABAPENTIN 400 mg capsules - orange capsule printed with "G 400" in blue ink containing a white crystalline powder. (AUST R 335739).

### **Who distributes APX-GABAPENTIN**

Arrotex Pharmaceuticals Pty Ltd  
15-17 Chapel Street  
Cremorne  
VIC, 3121  
[www.arrotex.com.au](http://www.arrotex.com.au)

This leaflet was prepared in August 2024.