

Cipla Pregabalin

Consumer Medicine Information (CMI) summary

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

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

1. Why am I using Cipla Pregabalin?

Cipla Pregabalin contains the active ingredient, pregabalin. Cipla Pregabalin is taken to treat neuropathic pain, which is pain caused by an abnormality of, or damage to, the nerves. Cipla Pregabalin is also used to control epilepsy which is a condition where you have repeated seizures (fits) For more information, see Section [1. Why am I using Cipla Pregabalin?](#) in the full CMI.

2. What should I know before I use Cipla Pregabalin?

Do not use if you have ever had an allergic reaction to 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 use Cipla Pregabalin?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Cipla 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 use Cipla Pregabalin?

Cipla Pregabalin should be administered once daily after an evening meal. It should be swallowed whole and should not be split, crushed or chewed. More instructions can be found in Section [4. How do I use Cipla Pregabalin?](#) in the full CMI.

5. What should I know while using Cipla Pregabalin?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Cipla Pregabalin.• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.• Tell your doctor immediately if you experience any changes in your vision, trouble breathing or shallow breaths.• 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.
Things you should not do	<ul style="list-style-type: none">• Do not take Cipla Pregabalin to treat any other complaints unless your doctor tells you to.• Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how Cipla Pregabalin affects you.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol while you are taking this medicine.
Looking after your medicine	<ul style="list-style-type: none">• Keep your capsules in a cool dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

Tell your doctor or pharmacist if you notice any of the following less serious side effects and they worry you: dizziness, feeling tired or drowsy, constipation, diarrhoea, nausea, headache, increase in weight, unsteadiness when walking, reduced coordination, shaking or tremors, dry mouth, blurred or double vision. **Tell your doctor as soon as possible if you notice any of the following more serious side effects:** unusual changes in mood or behaviour, signs of new or increased irritability or agitation, signs of depression, confusion, swelling of the hands, ankles or feet, enlargement of breasts, unexplained muscle pain, tenderness and weakness, passing little to no urine, trouble breathing, shallow breath. 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 Cipla Pregabalin, tell your doctor if you have a history of drug abuse. Pregabalin poses risks of misuse, abuse and dependence. Using Cipla 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.

Cipla Pregabalin

Pregabalin

Consumer Medicine Information (CMI)

This leaflet provides important information about using Cipla 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 using Cipla Pregabalin.**

Where to find information in this leaflet:

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

1. Why am I using Cipla Pregabalin?

Cipla Pregabalin contains the active ingredient, pregabalin.

Cipla Pregabalin 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. Cipla Pregabalin also has pain relieving effects.

Cipla Pregabalin is used to treat neuropathic pain, which is pain caused by an abnormality of, or damage to, the nerves.

Cipla Pregabalin 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.

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

Your doctor may prescribe Cipla 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 it for another reason.

2. What should I know before I use Cipla Pregabalin?

Warnings

Do not use Cipla 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 use 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.

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 such as:
 - congestive heart failure,
 - hereditary problems with galactose metabolism
 - kidney problems,
 - diabetes,
 - Depression.

- have a history of drug abuse.

Pregabalin poses risks of misuse, abuse and dependence. Your body may become used to you taking Cipla Pregabalin and this may result in physical dependence. It means that you may experience withdrawal symptoms if you stop taking Cipla 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.

Cipla 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 Cipla Pregabalin, your doctor can help you decide whether or not to take it 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.

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

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

Some medicines may be affected by Cipla Pregabalin 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. **Using Cipla 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.

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

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

4. How do I use Cipla Pregabalin?

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

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

How much to take

- Your doctor will tell you how much Cipla Pregabalin to take. 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 Cipla 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.

When to take Cipla Pregabalin

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 Cipla Pregabalin

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

If you forget to use Cipla Pregabalin

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 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 use too much Cipla Pregabalin

If you think that you or anyone else may have used too much Cipla Pregabalin, urgent medical attention may be needed.

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.

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

5. What should I know while using Cipla Pregabalin?

Things you should do

- If you are about to be started on any new medicine remind any doctor, dentist or pharmacist you visit that you are using Cipla Pregabalin.
- 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 if you feel Cipla Pregabalin is not helping your condition.
Your doctor may need to change your medicine.

- Tell your doctor if, for any reason, you have not taken Cipla Pregabalin exactly as prescribed. Otherwise, your doctor may change your treatment unnecessarily.
- 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.

Call your doctor straight away if you:

- experience any changes in your vision: Cipla Pregabalin may cause blurring or other changes in eyesight. Your doctor may ask you to stop taking Cipla Pregabalin to improve these symptoms.
- have any thoughts of suicide or self-harm, any unusual changes in mood or behaviour, or show signs of depression. Some people taking medicines to treat convulsions, such as Cipla 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:

- 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 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 Cipla Pregabalin, contact your doctor or a mental health professional right away.

- experience trouble breathing or shallow breaths. If you have nervous system or respiratory disorders, kidney problems, or you are older than 65, your doctor may adjust your dose.
- become pregnant while taking Cipla Pregabalin

Things you should not do

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

Driving or using machines

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

As with other anticonvulsant medicines, Cipla Pregabalin may cause dizziness in some people, with other

anticonvulsant medicines. If you have any of these symptoms, do not drive, operate machinery or do not do anything else that could be dangerous

Drinking alcohol

Be careful when drinking alcohol while you are taking this medicine

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

Looking after your medicine

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

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 children cannot reach it.

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

6. Are there any side effects?

Cipla 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. 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 **Cipla 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.

Do not be alarmed by the list of side effects.

You may not experience any of them.

If you get any side effects, do not stop taking Cipla Pregabalin without first talking to your doctor or pharmacist.

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
<p>Nervous system related</p> <ul style="list-style-type: none"> • dizziness • feeling tired or drowsy • headache • unsteadiness when walking, reduced co-ordination, shaking or tremors <p>Gastrointestinal related</p> <ul style="list-style-type: none"> • constipation • diarrhoea • nausea • dry mouth <p>Metabolism related</p> <ul style="list-style-type: none"> • increase in weight <p>Eye related</p> <ul style="list-style-type: none"> • blurred or double vision. <p>The above list includes the more common side effects of your medicine. They are usually mild and short-lived.</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Psychiatric related ;</p> <ul style="list-style-type: none"> • unusual changes in mood or behaviour • signs of new or increased irritability, or agitation • signs of depression • confusion <p>Musculoskeletal related</p> <ul style="list-style-type: none"> • unexplained muscle pain, tenderness and weakness <p>Respiratory related</p> <ul style="list-style-type: none"> • trouble breathing, shallow breaths <p>Other side effects:</p> <ul style="list-style-type: none"> • passing little to no urine • swelling of the hands, ankles or feet • enlargement of breasts 	<p>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.</p>

More serious side effects

More serious side effects	What to do
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<p>Respiratory related:</p> <ul style="list-style-type: none"> • shortness of breath <p>Eye related</p> <ul style="list-style-type: none"> • irritated red eyes that are sensitive to light <p>Neurological related:</p> <ul style="list-style-type: none"> • more frequent or more severe seizures (fits) <p>Allergy related:</p> <ul style="list-style-type: none"> • rash, itching or hives • reddish non-elevated, target-like or circular patches on the trunk, often with central blisters • skin peeling • swelling of the face, lips, tongue or other parts of the body • shortness of breath, wheezing or difficulty breathing <p>Skin related</p> <ul style="list-style-type: none"> • serious skin reactions characterized by 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 flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis) <p>Other side effects:</p> <ul style="list-style-type: none"> • swelling of the feet and legs • weight increase due to fluid build-up • ulcers of mouth, throat, nose, genitals and eyes <p>The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.</p>	<p>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.</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 blood pressure) can only be found when your doctor does tests from time to time to check your progress.

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. 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 Cipla Pregabalin contains

Active ingredient (main ingredient)	Pregabalin
Other ingredients (inactive ingredients)	<p>Starch, Talc</p> <p>The capsule shells (cap and body) contain:</p> <p><u>25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg capsule</u></p> <p>Gelatin,</p> <p>Sodium lauryl sulphate,</p> <p>Titanium dioxide.</p> <p><u>75 mg, 100 mg, 200 mg, 225 mg, 300 mg capsule</u></p> <p>FD&C Blue 1,</p> <p>FD&C Red 40,</p> <p>FD&C Yellow 6.</p> <p><u>Printing ink contains:</u></p> <p>Black iron oxide,</p> <p>Butyl alcohol,</p> <p>Dehydrated alcohol,</p> <p>Isopropyl alcohol,</p> <p>Potassium hydroxide,</p> <p>Propylene glycol,</p> <p>Shellac,</p> <p>Strong ammonia solution.</p>

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

What Cipla Pregabalin looks like

25 mg - white to off white powder filled in size '4' hard gelatin white opaque and white opaque capsule linear

printed in black ink with 'Cipla 25 mg' on the cap and '677' on the body.

50 mg - white to off white powder filled in size '3' hard gelatin white opaque and white opaque capsule linear printed in black ink with 'Cipla 50 mg' on the cap and '678' on the body.

75 mg - white to off white powder filled in size '4' hard gelatin orange opaque and white opaque capsule linear printed in black ink with 'Cipla 75 mg' on the cap and '679' on the body.

100 mg - white to off white powder filled in size '3' hard gelatin orange opaque and orange opaque capsule linear printed in black ink with 'Cipla 100 mg' on the cap and '681' on the body.

150 mg - white to off white powder filled in size '2' hard gelatin white opaque and white opaque capsule linear printed in black ink with 'Cipla 150 mg' on the cap and '682' on the body.

200 mg - white to off white powder filled in size '1' hard gelatin light orange opaque and light orange opaque capsule linear printed in black ink with 'Cipla 200 mg' on the cap and '683' on the body.

225 mg - white to off white powder filled in size '1' hard gelatin light orange opaque and white opaque capsule linear printed in black ink with 'Cipla 225 mg' on the cap and '684' on the body.

300 mg - white to off white powder filled in size '0' hard gelatin orange opaque and white opaque capsule linear printed in black ink with 'Cipla 300 mg' on the cap and '685' on the body.

Each blister pack contains 10's, 14's and 56 capsules and in HDPE container with child-resistant cap for 30's and 90's capsules or in HDPE container with screw cap for 500's capsules.

Pack size of 90's and 500's capsules are for dispensing use only.

Blister pack-

AUST R 317646, AUST R 317664,
AUST R 317666, AUST R 317671,
AUST R 317673, AUST R 317677,
AUST R 317679, AUST R 317681

Bottle pack

AUST R 317663, AUST R 317665,
AUST R 317667, AUST R 317672,
AUST R 317674, AUST R 317678,
AUST R 317680, AUST R 317682

Who distributes Cipla Pregabalin

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