LYZALON

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 LYZALON?

LYZALON contains the active ingredient pregabalin. LYZALON is used to treat neuropathic pain, which is pain caused by an abnormality of, or damage to, the nerves. LYZALON 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 LYZALON? in the full CMI.

2. What should I know before I use LYZALON?

Do not use if you have ever had an allergic reaction to LYZALON 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 use LYZALON? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LYZALON 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 LYZALON?

The usual dose range is 150 mg per day to 600 mg per day given in two divided doses. Swallow the capsules whole with a full glass of water. More instructions can be found in Section 4. How do I use LYZALON? in the full CMI.

5. What should I know while using LYZALON?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using LYZALON. • 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	• Do not take LYZALON 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	• Be careful driving or operating machinery until you know how LYZALON affects you.
Drinking alcohol	• Be careful when drinking alcohol while you are taking this medicine.
Looking after your medicine	• Keep LYZALON in a cool dry place where the temperature stays below 25°C. • Keep it where children cannot reach it.

For more information, see Section 5. What should I know while using LYZALON? 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 effect 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 or 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 breaths. 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 LYZALON, tell your doctor if you have a history of drug abuse. LYZALON poses risks of misuse, abuse and dependence. Using LYZALON 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.

LYZALON

Active ingredient(s): *Pregabalin* (PRE-gab-a-lin)

Consumer Medicine Information (CMI)

This leaflet provides important information about using LYZALON. **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 LYZALON.**

Where to find information in this leaflet:

1. Why am I using LYZALON?
2. What should I know before I use LYZALON?
3. What if I am taking other medicines?
4. How do I take LYZALON?
5. What should I know while using LYZALON?
6. Are there any side effects?
7. Product details

1. Why am I using LYZALON?

LYZALON contains the active ingredient pregabalin. LYZALON 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. LYZALON also has pain relieving effects.

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

LYZALON 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.

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

Your doctor may prescribe LYZALON 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.

Use in Children

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

2. What should I know before I use LYZALON?

Warnings

Do not use LYZALON if:

- you are allergic to pregabalin, 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 use this medicine.
- **the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.**

  If the capsules have expired or the pack is damaged, return to your pharmacist for disposal.

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

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 or have had any of the following medical conditions:
  - congestive heart failure
  - hereditary problems with galactose metabolism
  - kidney problems
  - diabetes
  - depression
- **have a history of drug abuse**

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

If you have not told your doctor about any of the above, tell them before you start taking LYZALON.

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

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

LYZALON 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 LYZALON, 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 LYZALON passes into breast milk and its safety in infants is unknown. It is recommended that you do not breast-feed while taking LYZALON.

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 LYZALON 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 LYZALON 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.

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

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

4. How do I take LYZALON?

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

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 LYZALON

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

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 LYZALON may include mood changes, feeling tired, confusion, depression, agitation, restlessness or seizures.

5. What should I know while using LYZALON?

Things you must do

- **If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are taking LYZALON.**
- **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 LYZALON is not helping your condition.**

  Your doctor may need to change your medicine.
- **Tell your doctor if, for any reason, you have not taken LYZALON 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.**

  LYZALON may cause blurring or other changes in eyesight. Your doctor may ask you to stop taking LYZALON 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 LYZALON, 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 LYZALON, 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 LYZALON**

Things you must not do

- **Do not take LYZALON 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 LYZALON affects you.

As with other anticonvulsant medicines, LYZALON 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.

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 the pack until it is time to take them.

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

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

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.

Heat and dampness can destroy some medicines.

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 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.

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 LYZALON.

LYZALON 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 LYZALON, 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 LYZALON 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 the side effects.

Less serious side effects

Less serious side effects	What to do
Nervous system related: • dizziness • feeling tired or drowsy • headache • unsteadiness when walking, reduced co-ordination, shaking or tremors **Gastrointestinal related:** • constipation • diarrhoea • nausea • dry mouth **Eye related:** • blurred or double vision **Metabolism related:** • increase in weight The above list includes the more common side effects of your medicine. They are usually mild and short-lived.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Psychiatric related: • unusual changes in mood or behaviour • signs of new or increased irritability or agitation • signs of depression • confusion **Musculoskeletal related:** • unexplained muscle pain, tenderness and weakness **Respiratory related:** • trouble breathing, shallow breaths. **Other side effects:** • passing little to no urine • swelling of the hands, ankles or feet • enlargement of breasts The above list includes serious side effects that may require medical attention. Serious side effects are rare.	**Call your doctor straight away if you notice any of these serious side effects.**

More serious side effects

More serious side effects	What to do
Respiratory related: • shortness of breath **Eye related:** • irritated red eyes that are sensitive to light **Neurological related:** • more frequent or more severe seizures (fits) **Allergy related:** • 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	**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.**

More serious side effects	What to do
• shortness of breath, wheezing or difficulty breathing **Skin related** • serious skin reactions characterised 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). **Other side effects:** • swelling of the feet and legs • weight increase due to fluid build-up • ulcers of mouth, throat, nose, genitals and eyes 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 else that may be making you feel unwell.

Other side effects not listed above may also 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 LYZALON contains

Active ingredient (main ingredient)	• LYZALON 25 mg capsules: 25 mg pregabalin • LYZALON 75 mg capsules: 75 mg pregabalin • LYZALON 150 mg capsules: 150 mg pregabalin • LYZALON 300 mg capsules: 300 mg pregabalin
Other ingredients (inactive ingredients)	• Pregelatinised maize starch • Purified talc • Gelatin • Sodium lauryl sulfate • Titanium dioxide • Iron oxide red (75 mg and 300 mg capsules only) • The capsules have a trace of TekPrint SW-9008 black ink

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

What LYZALON looks like

25 mg - White opaque/White opaque, size “4” hard gelatin capsules imprinted with ‘PG’ on cap and ‘25’ on body containing white to off white powder. Packaged in Alu-Alu blister and PVC-Alu blister packs containing 14, 21, 56, 60 or 84 hard capsules and HDPE bottle packs containing 14, 20, 30, 56, 60, 200 or 500 hard capsules.

Lyzalon 25 mg blister pack: AUST R 235868

Lyzalon 25 mg bottle pack: AUST R 235836

75mg - Red opaque/White opaque, size “4” hard gelatin capsules imprinted with ‘PG’ on cap and ‘75’ on body containing white to off white powder. Packaged in Alu-Alu blister and PVC-Alu blister packs containing 14, 21, 56, 60 or 84 hard capsules and HDPE bottle packs containing 14, 20, 30, 56, 60, 200 or 500 hard capsules.

Lyzalon 75 mg blister pack: AUST R 235865

Lyzalon 75 mg bottle pack: AUST R 235858

150 mg - White opaque/White opaque, size “2” hard gelatin capsules imprinted with ‘PG’ on cap and ‘150’ on body containing white to off white powder. Packaged in Alu-Alu blister and PVC-Alu blister packs containing 14, 21, 56, 60 or 84 hard capsules and HDPE bottle packs containing 14, 20, 30, 56, 60, 200 or 500 hard capsules.

Lyzalon 150 mg blister pack: AUST R 235856

Lyzalon 150 mg bottle pack: AUST R 235867

300 mg - Red opaque/White opaque, size “0” hard gelatin capsules imprinted with ‘PG’ on cap and ‘300’ on body containing white to off white powder. Packaged in Alu-Alu blister and PVC-Alu blister packs containing 14, 21, 56, 60 or 84 hard capsules and HDPE bottle packs containing 14, 20, 30, 56, 60, 200 or 500 hard capsules.

Lyzalon 300 mg blister pack: AUST R 235839

Lyzalon 300 mg bottle pack: AUST R 235875

Some pack sizes may not be marketed.

Sponsor

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne VIC 3000
Australia

Distributor

LYZALON is distributed in Australia by:
Alphapharm Pty Ltd trading as Viatris
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

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