

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.

1. Why am I using Lexotan?

Lexotan contains the active ingredient bromazepam. Lexotan is used for anxiety, tension or agitation.

For more information, see Section [1. Why am I using Lexotan?](#) in the full CMI.

2. What should I know before I use Lexotan?

Do not use if you have ever had an allergic reaction to Lexotan or any of the ingredients listed at the end of the CMI. The use of Lexotan may lead to dependence on the medicine. **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 Lexotan?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Lexotan 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 Lexotan?

- Take Lexotan exactly as your doctor has prescribed. Your doctor will tell you how many Lexotan tablets to take each day.
- The dose varies from person to person depending on age and the condition being treated. The usual dose is between 6 to 12 mg daily. Elderly patients may need to take less.
- Lexotan should be used for short periods only (for example 2 to 4 weeks). Continuous long-term use is not recommended unless advised by your doctor.

More instructions can be found in Section [4. How do I use Lexotan?](#) in the full CMI.

5. What should I know while using Lexotan?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Lexotan.• Do not take any other medicines without first telling your doctor.• Tell your doctor if you become pregnant while taking Lexotan.
Things you should not do	<ul style="list-style-type: none">• Do not take Lexotan for a longer time than your doctor has prescribed.• Do not stop taking Lexotan or lower the dose, without first checking with your doctor, especially if you have epilepsy.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery until you know how Lexotan affects you.
Drinking alcohol	<ul style="list-style-type: none">• Alcohol may increase the effects of Lexotan. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are using Lexotan.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C.• Store in a cool, dry place away from young children.

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

6. Are there any side effects?

Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of the following serious side effects: sudden anxiety or excitement, restlessness, agitation, irritability, anger, abnormal behaviour, hallucinations, delusions, severe sleep disturbances, or difficulties in breathing or shortness of breath. Speak to your doctor if you have any of the following less side effects and they worry you: drowsiness, tiredness, dizziness, unsteadiness, loss of memory, inattentiveness, confusion, lack of concentration, headache, hangover feeling in the morning, slurred speech, or unpleasant dreams. 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.

Lexotan®

Active ingredient(s): bromazepam

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Lexotan?

Lexotan contains the active ingredient bromazepam.

Lexotan belongs to a group of medicines called benzodiazepines, which are thought to work by their action on brain chemicals.

Lexotan is used to for anxiety. Anxiety or tension associated with the normal stress of everyday life usually does not require treatment with medicines.

Your doctor, however, may have prescribed Lexotan for another purpose.

Ask your doctor if you have any questions why Lexotan has been prescribed for you.

In general, benzodiazepines such as Lexotan should be taken for short time periods only (for example 2 to 4 weeks). Continuous long-term use is not recommended unless advised by your doctor.

This medicine may be addictive.

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

2. What should I know before I use Lexotan?

Warnings

Lexotan is not recommended as the first choice of treatment of depression, anxiety and/or mental disorder as it can increase the risk of suicide.

Do not use Lexotan if:

- you are allergic to bromazepam, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- you have severe and chronic lung disease
- you have severe liver disease

- you have temporary stops in breathing during sleep
- you suffer from severe muscle weakness
- the package is torn or shows signs of tampering
- the expiry date (EXP) printed on the pack has passed

Check with your doctor if you:

- have any other medical conditions, including:
 - liver, kidney or lung disease
 - high or low blood pressure
 - depression, schizophrenia or other mental illness
 - glaucoma (high pressure in the eye)
 - epilepsy (fits)
 - history of alcohol or drug abuse
- take any medicines for any other condition
- drink alcohol. Alcohol may increase the effects of Lexotan.
- Are allergic to any other medicines, foods, dyes or preservatives.

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.

Lexotan is not recommended for use in pregnant women. Your doctor will discuss the risks and benefits of using Lexotan if you are pregnant or plan to become pregnant.

Lexotan crosses the placenta and may cause decreased muscle tone, breathing difficulties and sudden drop in body temperature in the newborn infant. Newborn infants born to mothers that have taken this type of medicine throughout pregnancy may be at risk of developing withdrawal symptoms.

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

Lexotan passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected. Lexotan is not recommended for use whilst breast-feeding.

Use in children

- Do not give Lexotan to children

Dependence

- The use of benzodiazepines (such as Lexotan) may lead to dependence on the medicine.

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 Lexotan and affect how it works, and some medicines may be affected by Lexotan. These medicines include:

- other sleeping tablets, sedatives or tranquilizers
- medicines for depression
- medicines to control fits
- medicines for allergies or colds such as antihistamines
- pain relievers
- muscle relaxants
- cimetidine - a medicine used to treat ulcers
- dilsulfiram - a medicine used in alcohol abuse

Taking central nervous system depressants/ sedatives

Taking central nervous system depressants, such as sedatives, tranquilizers, and hypnotics, while taking Lexotan, have the potential to significantly increase the effects on Lexotan and may lead to addiction or result in death from overdose.

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

4. How do I use Lexotan?

How much to take

- Take Lexotan exactly as your doctor has prescribed. Your doctor will tell you how many Lexotan tablets to take each day. The dose varies from person to person depending on age and the condition being treated.
- The usual dose is between 6 to 12 mg daily. Elderly patients may need to take less.
- Lexotan should be used for short periods only (for example 2 to 4 weeks). Continuous long-term use is not recommended unless advised by your doctor.
- Do not stop taking Lexotan or lower the dose, without first checking with your doctor.

When to take Lexotan

- Lexotan should be taken as directed by your doctor.

How to Lexotan

- It should be taken on an empty stomach, 30 to 60 minutes before food.

If you forget to use Lexotan

Lexotan should be used regularly at the same time each day.

If it is almost time for your next dose, 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.

If you use too much Lexotan

If you think that you have used too much Lexotan, you may need urgent medical attention.

If you have taken too much Lexotan, you may feel drowsy, tired, confused, dizzy, have difficulty breathing, feel weak or become unconscious.

It is important that you recognize these signs of overdose early and take immediate action below.

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 using Lexotan?

Things you should do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Lexotan.

Do not take any other medicines whether they require a prescription or not without first telling your doctor.

All mentions of suicide or violence must be taken seriously. Tell your doctor or a mental health professional immediately if you experience mood changes, restlessness, aggression, rage, hallucinations or any adverse behavioural or unusual behaviour.

Call your doctor straight away if you:

- become pregnant while taking Lexotan
- have not taken your medicine exactly as prescribed
- you feel the tablets are not helping your condition

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Remind any doctor, dentist or pharmacist you visit that you are using Lexotan.

Things you should not do

- Do not take Lexotan for a longer time than your doctor has prescribed. Lexotan should be taken for short periods only (for example, 2-4 weeks) unless advised by your doctor.
- Do not stop taking Lexotan or lower the dose without first checking with your doctor. Stopping this medicine suddenly may cause some unwanted effects. Your doctor will explain how you should slowly reduce your dose of Lexotan before you can stop taking it completely.
- Do not suddenly stop taking Lexotan if you suffer from epilepsy. Stopping this medicine suddenly may make your epilepsy worse.
- Do not give Lexotan to anyone else even if they have the same condition as you.
- Do not use Lexotan to treat other complaints unless your doctor says to.

Things to be careful of

Be careful if you are elderly, unwell, drinking alcohol or taking other medicines.

- Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness which may increase the risk of a fall.

Do not drive or use any machines or tools until you know how Lexotan affects you.

Lexotan may cause drowsiness or dizziness in some people and therefore may affect alertness. Make sure you know how you react to Lexotan before your drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may increase the effects of Lexotan. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking Lexotan.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.

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

Store it in a cool dry place where the temperature stays below 30°C, 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 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?

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
<ul style="list-style-type: none">• drowsiness, tiredness• dizziness• loss of memory, inattentiveness, confusion, lack of concentration• slurred speech• unpleasant dreams	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
<ul style="list-style-type: none">• blurred vision• rash• tremor• loss of appetite• dry mouth• slurred speech• loss of memory, inattentiveness, confusion, lack of concentration• sudden anxiety or excitation• seeing, feeling or hearing things that are not there• nightmares• shortness of breath or difficulty in breathing• fast, irregular heartbeat with feelings of dizziness or difficulty breathing• cardiac arrest	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.

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. 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 Lexotan contains

Active ingredient (main ingredient)	Bromazepam
Other ingredients	lactose monohydrate

(inactive ingredients)	microcrystalline cellulose purified talc magnesium stearate iron oxide red (3mg) indigo carmine aluminium lake (6mg) iron oxide yellow (6mg)
Potential allergens	None. Lexotan tablets are gluten-free.

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

What Lexotan looks like

Lexotan 3 mg tablets are pale red, slightly speckled, cylindrical, biplanar tablets marked with /3 on one side and a simple break mark on the other side.

(Aust R 52269).

Lexotan 6 mg tablets are greenishgrey to greyish-green, slightly speckled, cylindrical, biplanar tablets marked with /6 on one side and a simple break mark on the other side.

(Aust R 52270).

Who distributes Lexotan

Pharmaco Australia Ltd
Level 13, 465 Victoria Avenue
Chatswood
NSW
2067
Phone: 1800 210 564

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Arzneimittel GmbH, Germany

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