

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LEXOTAN.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking LEXOTAN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What LEXOTAN is used for

LEXOTAN contains the active ingredient bromazepam.

LEXOTAN belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

LEXOTAN is used for anxiety, tension or agitation. 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 periods only (for example 2 - 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.

Before you take LEXOTAN

Do not take LEXOTAN if:

- 1. you have had an allergic reaction to LEXOTAN, other benzodiazepines or any 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

- 2. you have severe and chronic lung disease**
- 3. you have severe liver disease**
- 4. you suffer from sleep apnoea (temporary stops in breathing during sleep)**
- 5. you have muscle weakness known as myasthenia gravis**
- 6. the package is torn or shows signs of tampering**
- 7. the expiry date (EXP) printed on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work as well.

Do not give LEXOTAN to children.

Safety and effectiveness in children have not been established.

If you are not sure if you should be taking LEXOTAN, talk to your doctor.

Before you start to take it:

Your doctor must know about all the following before you start to take LEXOTAN.

Tell your doctor if:

- 1. you are pregnant or plan to become pregnant**

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

- 2. you are breast-feeding or plan to breast-feed**

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 while breast-feeding.

- 3. you have any other health problems, especially the following:**

- liver, kidney or lung disease
- high or low blood pressure
- you suffer from depression, psychosis or schizophrenia
- you suffer from fits or convulsions (epilepsy)
- you have high pressure in the eye (glaucoma).

- 4. you drink alcohol regularly**

Alcohol may increase the effects of LEXOTAN.

5. **you are lactose intolerant**
6. **you are allergic to any other medicines, foods, dyes or preservatives.**

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

Taking other medicines

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

Some medicines may interfere with LEXOTAN. These medicines include:

- other sleeping tablets, sedatives or tranquillisers
- other medicines for anxiety
- medicines used to treat certain mental and emotional conditions
- medicines for depression
- medicines to control fits (epilepsy)
- some medicines used to treat allergies and colds
- pain relievers
- muscle relaxants
- anaesthetics
- some medicines used to treat bacterial infections
- some medicines used to treat HIV infection
- some medicines used to treat heart conditions or high blood pressure
- cimetidine – a medicine used to treat ulcers
- disulfiram – a medicine used in alcohol abuse

These medicines may be affected by LEXOTAN, or may affect how well LEXOTAN works. You may need to use different amounts of your medicine, or you may need to take

different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking LEXOTAN.

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

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take LEXOTAN

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 box, ask your doctor or pharmacist for help.

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 - 12 mg daily. Elderly patients may need to take less.

How to take it

Swallow the tablets whole with a glass of water.

When to take it

Take the tablets as directed by your doctor. It may be taken with or without food.

How long to take it

Do not use LEXOTAN for longer than your doctor says.

Usually LEXOTAN should be used for short periods only (for example 2 - 4 weeks). Continuous long-term use is not recommended unless advised by your doctor.

The use of benzodiazepines may lead to dependence on the medicine.

If you forget to take it

If it is almost time for your next dose, 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 it as you would normally.

Do not try to make up for the dose that you missed by taking more than one dose at a time.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering your dose, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much LEXOTAN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much LEXOTAN you may feel drowsy, confused,

tired, dizzy, have difficulty breathing, feel weak or become unconscious.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking LEXOTAN

Things you must 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.

Tell your doctor if you become pregnant while taking LEXOTAN.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if 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.

Things you must not do

Do not drive or operate machinery 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 you drive a

car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Even if you take LEXOTAN at night, you may still be drowsy or dizzy the next day.

Do not take LEXOTAN for a longer time than your doctor has prescribed.

LEXOTAN should be taken for short periods only (for example 2 to 4 weeks), unless advised otherwise by your doctor.

Do not change your dose without first checking with 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.

Suddenly stopping this medicine 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 when drinking alcohol while taking LEXOTAN.

Combining LEXOTAN and alcohol may make you more sleepy, dizzy or lightheaded.

Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking LEXOTAN.

Be careful if you are elderly, unwell 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LEXOTAN.

LEXOTAN helps most people with anxiety 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 treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- drowsiness, tiredness
- dizziness
- headache
- unpleasant dreams
- muscle weakness

These are the more common side effects of LEXOTAN.

Tell your doctor as soon as possible if you notice any of the following and they worry you:

- blurred vision
- rash
- tremor
- loss of appetite
- dry mouth
- slurred speech

- loss of memory, inattentiveness, confusion, lack of concentration

Tell your doctor immediately if you notice any of the following:

- sudden anxiety or excitation
- seeing, feeling or hearing things that are not there
- nightmares

These are serious side effects and you may need medical attention.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- shortness of breath or difficulty in breathing

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking LEXOTAN

Storage

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

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

Keep LEXOTAN in a cool dry place where the temperature stays below 30°C.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep LEXOTAN 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.

Disposal

If your doctor tells you to stop taking LEXOTAN, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

Availability

LEXOTAN comes in two tablet strengths, 3 mg and 6 mg.

LEXOTAN 3 mg tablets come in packs of 30.

LEXOTAN 6 mg tablets come in packs of 30.

What LEXOTAN looks like

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

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

Ingredients

Active ingredient - bromazepam

- each 3 mg tablet contains 3 mg bromazepam
- each 6 mg tablet contains 6 mg bromazepam

Inactive ingredients -

3 mg and 6 mg tablets contain

- lactose
- microcrystalline cellulose (460)
- talc (553)
- magnesium stearate (470)

The 3 mg tablets also contain the colouring agent

- iron oxide red CI 77491 (172(ii))

The 6 mg tablets also contain the colouring agents

- indigotine CI 73015 (132)
- iron oxide yellow, CI 77492 (172 (iii))

LEXOTAN tablets are gluten free.

Distributor

LEXOTAN is distributed by:

Roche Products Pty Limited
 ABN 70 000 132 865
 4-10 Inman Road
 Dee Why NSW 2099

Customer enquiries: 1 800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Numbers

- LEXOTAN 3 mg tablets AUST R 52269
- LEXOTAN 6 mg tablets AUST R 52270

This leaflet was prepared on 21 April 2009.