

# LEXOTAN<sup>®</sup>

Bromazepam (1.5 mg tablet)

## What is in this leaflet

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### 1. What Lexotan is used for

Lexotan contains the active ingredient bromazepam.

Lexotan is used to treat the following:

- *Emotional disturbances.* Acute tension and anxiety states. Difficulties in interpersonal contact. Agitation, insomnia. Anxious, agitated depressive reactions.
- *Functional disturbances in the heart and lung systems* (pseudoangina pectoris, precordial anxiety, tachycardia, emotiogenic hypertension, dyspnea, hyperventilation)
- *In the gastrointestinal system* (irritable bowel syndrome, epigastric pain, spasm, bloating diarrhea, etc.)
- *In the genitourinary system* (frequency, irritable bladder; dysmenorrhea).
- *Psychosomatic disorders.* Headache or skin problems caused by mental disturbances. Asthma. Gastric and duodenal ulcer, ulcerative colitis
- *Emotional reactions to chronic organic disease.*

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.

This medicine may be addictive.

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

### 2. How Lexotan works

Lexotan belongs to a group of medicines called benzodiazepines.

They are thought to work by their action on brain chemicals.

### 3. Before you use Lexotan

- When you must not use it

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. **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.

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

- Before you start to use it

Inform 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 breastfeeding or plan 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 while breast-feeding.

3. **You have any other health problems including:**

- Liver, kidney or lung disease

- You suffer from depression, psychosis or schizophrenia

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 tranquilisers
- 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

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.

Taking Lexotan with an opioid medicine (medicine to relieve pain) can depress your central nervous

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system. Inform your doctor if you are currently taking any opioid medicine.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

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.

## 4. How to use 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 use  
**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 average dosing for outpatient therapy is 1 to 2 tablets up to three times daily.

Severe cases, especially in hospital may need 4 to 8 tablets, two or three times daily.

Elderly patients may need to take less.

- How to use it  
Swallow the tablets whole with a glass of water.

- When to use it  
Take the tablets as directed by your doctor. It may be taken with or without food.

- How long to use it  
Do not use Lexotan for longer than your doctor says.

Usually Lexotan should not be used more than 8-12 weeks, including a tapering off process. 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 use 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 use too much (overdose)  
You may need urgent medical attention. Contact your doctor or visit the nearest Accident & Emergency Department immediately (bring along the medication, carton and this leaflet if possible).

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

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

## 5. While you are using 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, 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.

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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 so.

- 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.

## 6. While you are using Lexotan

**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.

**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

- Loss of memory, inattentiveness, confusion, lack of concentration.

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

- Sudden anxiety or excitement
- 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 effects which are 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) [Public → Reporting Side Effects to Medicines (ConSERF) or Vaccine (AEFI)]

## 7. Storage and disposal of 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.

- Disposal

Medicinal products should not be poured down the drain or thrown into household waste. Ask your pharmacist how to dispose of packaging and medicinal products you do not need. This will help protect the environment.

## 8. Product Description

- What Lexotan looks like

Lexotan 1.5 mg tablets are slightly yellowish, cylindrical, biplane tablets marked with /1.5 on one side and a simple break mark on the other side.

### Ingredients

**Active ingredient:**

Each 1.5 mg tablet contains 1.5 mg bromazepam

**Inactive ingredients:**

- Lactose
- Microcrystalline cellulose
- Talc
- Magnesium stearate

- MAL number:

MAL19861302ACRZ

## 9. Manufacturer and Product Registration Holder

Made for CHEPLAPHARM Arzneimittel GmbH by Aesica Pharmaceuticals GmbH, Zwickau, Germany

### Product Registration Holder

DKSH Malaysia Sdn Bhd  
B-11-01, The Ascent, Paradigm,  
No.1, Jalan SS7/26A, Kelana Jaya,  
47301 Petaling Jaya, Selangor Darul  
Ehsan, Malaysia.

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