

Package leaflet: Information for the patient

Lexotan 1.5 mg Tablets

Lexotan 3 mg Tablets

Bromazepam

Please read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lexotan is and what it is used for
2. What you need to know before you take Lexotan
3. How to take Lexotan
4. Possible side effects
5. How to store Lexotan
6. Contents of the pack and other information

1. What Lexotan is and what it is used for

Lexotan contains a medicine called bromazepam. This belongs to a group of medicines called ‘benzodiazepines’.

Lexotan is used for severe anxiety (very strong fear or deep worry that can affect feelings, mood, behaviour and thinking patterns). Lexotan will be prescribed for as short a time as possible. This will normally be up to a maximum of 8 to 12 weeks.

2. What you need to know before you take Lexotan

Do not take Lexotan if you are allergic (hypersensitive) to:

- Bromazepam or any of the other ingredients of Lexotan (listed in Section 6: Contents of the pack and other information).
 - Other ‘benzodiazepine’ medicines. These include diazepam, clonazepam, flurazepam and temazepam.
- Do not take Lexotan if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Lexotan.

Do not take Lexotan if:

- You have severe breathing problems or lung disease.
- You have severe liver problems.
- You have a condition called ‘myasthenia gravis’ (where your muscles become weak and get tired easily).
- You have a condition called ‘sleep apnoea syndrome’ (where your breathing stops when you are asleep), so you may be closely monitored.

Do not take Lexotan if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Lexotan.

Children

Do not give Lexotan to children under 12 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lexotan if:

- You have liver, kidney or lung problems.
- You are being treated for depression.
- You take recreational drugs.
- You regularly drink alcohol. Alcohol can increase the clinical effects of Lexotan, possibly including severe sedation that could result in coma or death.
- You have had problems with alcohol or drug use in the past.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Lexotan.

Other medicines and Lexotan

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Lexotan can affect the way some other medicines work. Also some other medicines can affect the way Lexotan works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines to treat mental health problems (such as diazepam).
- Medicines to help you sleep (such as zolpidem).
- Medicines for allergies, which make you sleepy (such as diphenhydramine).
- Medicines to treat epilepsy (such as clozapine).
- Cimetidine (used to treat stomach problems and heartburn).
- Propranolol (used to treat high blood pressure, tremors, and chest pain).
- Fluvoxamine (used to treat obsessive-compulsive disorder and anxiety).
- Strong painkillers (such as morphine).
- Strong medicines for treating infections including HIV (for example, protease inhibitors).

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Lexotan.

Operations

If you are going to have an anaesthetic for an operation or for dental treatment, it is important to tell your doctor or dentist that you are taking Lexotan.

Drinking alcohol

Do not drink alcohol while you are taking Lexotan. This is because:

- Lexotan can make you feel sleepy.
- You are more likely to have problems with your concentration and to fall more deeply asleep.
- If you fall very deeply asleep this may cause serious problems with your breathing and heart beat.

Pregnancy and breast-feeding

Talk to your doctor before taking Lexotan if you are pregnant, or trying to get pregnant. Your doctor will then decide if you should take Lexotan. This is because Lexotan will affect your baby.

If you are already taking Lexotan talk to your doctor immediately, he will decide if you should stop taking this medicine.

It is not recommended to breast-feed if you are taking Lexotan as it can pass into your breast milk.

Driving and using machines

Talk to your doctor about driving and using machines or tools, whilst you are taking Lexotan. This is because it can make you feel sleepy, make it difficult to concentrate, forgetful and slow down your reactions. You should also read the section on 'Drinking alcohol'. If you are in any doubt about whether you can do a particular activity, talk to your doctor.

Important information about some of the ingredients of Lexotan

This medicine contains lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), contact your doctor before taking this medicinal product.

3. How to take Lexotan

Always take Lexotan exactly as your doctor has told you. You should check with your doctor if you are not sure.

- You will be started on a low dose of Lexotan. Your doctor will slowly increase it until you are taking the right dose for you. Your doctor will give you the lowest possible dose that works for you and check your treatment regularly to prevent an overdose caused by a build-up of Lexotan in your body.
- Your doctor will want you to take Lexotan for the shortest possible time.

The following effects have been seen with Lexotan use particularly in children and the elderly; restlessness, agitation, irritability, aggressiveness, anxiety, delusion, anger, nightmares, hallucinations (seeing and possibly hearing things that are not really there), psychoses (losing contact with reality) and inappropriate behaviour or other adverse behavioural effects. These reactions are also known as paradoxical reactions, which are outcomes that are opposite to the effects normally expected for the drug. If you experience these, your doctor will consider stopping Lexotan treatment.

Lexotan tablets should be swallowed with a drink of water.

- **Children** Lexotan is not recommended for use in children less than 12 years of age.

Adults

- The usual dose of Lexotan is between 3 mg and 18 mg a day, split into several doses.
- A reduction in dose for elderly patients is recommended. You will normally take this medicine for no more than 12 weeks.

The elderly and people with liver or kidney problems

Your doctor will decide how many tablets you should take, and how often. Your dose will be lower than the normal dose prescribed for other adults.

If you take more Lexotan than you should

- If you take more Lexotan than you should, or if someone else takes your Lexotan tablets by mistake, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.
- If you take too many tablets, you may feel drowsy or sleepy, have difficulty controlling your movements (lack of co-ordination), have slow or slurred speech or jerky eye movements.

If you forget to take Lexotan

- If you forget to take a dose, skip the missed dose. Then take the next dose when it is due.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Lexotan

- Do not stop taking your tablets without talking to your doctor.
- When you stop taking Lexotan, your anxiety may return and you may get withdrawal symptoms especially if you stop too quickly. For the symptoms you may have, see 'Withdrawal symptoms' in Section 4: Possible side effects.
- When it is time to lower your dose or stop taking Lexotan, this must be done slowly. This lowers the chances of you having withdrawal symptoms. Your doctor will tell you how to do this.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Lexotan can cause side effects, although not everybody will get them.

Stop taking Lexotan and see a doctor straight way if you notice any of the following serious side effects-you may need urgent medical treatment:

- Severe allergic reaction. The signs may include:
 - Sudden swelling of the throat, face, lips and mouth. This may make it difficult to breathe or swallow.
 - Sudden swelling of the hands, feet and ankles.
 - Skin rash or itching.
- Heart problems including heart failure (may be seen as breathlessness, swelling of the ankles, cough, tiredness and a racing heart) and cardiac arrest.
- Breathing problems (respiratory depression). Early signs include suddenly noisy, difficult and uneven breathing. Your skin may become blue.
- Being restless, aggressive, angry, irritable or agitated.
- Nightmares and seeing or possibly hearing things that are not really there (hallucinations).
- Mental problems such as, delusions (believing in things that are not real) or losing contact with reality.
- A change in your behaviour that is out of character.

When you start taking Lexotan you may notice the following effects:

- Feeling drowsy, sleepy and tired.
- Feeling emotional and mood disturbances.
- Being less alert.
- Feeling confused or disorientated.
- Headache.
- Feeling dizzy.
- Feeling sick or being sick (nausea and vomiting).
- Weak muscles.
- Poor co-ordination, including ataxia feeling unsteady when you walk.
- Problems with your eye-sight (double vision).

These effects usually go away after some time. If you are worried talk to your doctor or pharmacist.

The following effects may occur at any time during your treatment

- Difficulty remembering new things, this may be at the same time as changed or strange behaviour.
- Depression.
- Constipation or diarrhoea.
- Skin rashes, itchy skin and reddening of the skin.
- A higher or lower interest in sex.
- Difficulty passing water (urinating).

Unexpected effects have been seen with Lexotan use particularly in children and the elderly; restlessness, agitation, irritability, aggressiveness, delusion, anger, nightmares, hallucinations (seeing and possibly hearing things that are not really there), psychoses (losing contact with reality) and inappropriate behaviour, nervousness, anxiety, abnormal dreams, hyperactivity or other adverse behavioural effects.

Withdrawal symptoms

You can become dependent on benzodiazepine medicines, like Lexotan. This means that if you stop treatment suddenly, lower the dose too quickly, or your medication is changed to a different treatment, you may get withdrawal symptoms. The symptoms can include:

- Headache.
- Muscle pain and feeling restless.
- Feeling very worried, tense, confused or bad tempered.
- Diarrhoea.

Less common withdrawal symptoms include:

- Feeling sensitive to light, noise and touch.
- Seeing or hearing things that are not really there (hallucinations).
- Tingling and feeling numb in your arms and legs.
- Feeling lost or losing contact with reality.
- Fits (convulsions).

Injury:

- Patients taking benzodiazepine medicines are at risk of falling and breaking bones. This risk is increased in the elderly and those taking other sedatives (including alcohol).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

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5. How to store Lexotan

- Keep this medicine out of the sight and reach of children.
- Do not use Lexotan after the expiry date printed on the pack. The expiry date refers to the last day of that month.
- Keep Lexotan tablets in their original packaging to protect from light and moisture.
- Lexotan tablets should not be stored above 25°C.
- Do not throw away any medicines via household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lexotan contains

The active substance in Lexotan is bromazepam. Lexotan tablets come in two different strengths

- Each Lexotan 1.5 mg Tablet contains 1.5 mg (milligram) bromazepam.
- Each Lexotan 3 mg Tablet contains 3 mg (milligram) bromazepam.

The other ingredients in Lexotan tablets are microcrystalline cellulose, lactose monohydrate, magnesium stearate, talc. Lexotan 3 mg Tablets also contain iron oxide red (E172).

What Lexotan looks like and contents of the pack

- Lexotan 1.5 mg Tablets are cylindrical, off-white to slightly yellow in colour and marked 1.5.
- Lexotan 3 mg Tablets are cylindrical, pale red, slightly speckled in colour and marked 3.

Lexotan tablets are supplied in plastic bottles or blister packs:

- The blisters contain 4, 10, 20, 30, 60 or 100 tablets.
- The bottles contain 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This leaflet was last revised in December 2023