

**1.3.2 PATIENT INFORMATION LEAFLET****SCHEDULING STATUS**

S5

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

LEXOTAN® 3 (Tablets)

LEXOTAN® 6 (Tablets)

**Read all of this leaflet carefully before you start taking LEXOTAN**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- LEXOTAN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**WHAT LEXOTAN CONTAINS**

Each LEXOTAN 3 tablet contains 3 mg bromazepam.

The other ingredients are: microcrystalline cellulose, lactose monohydrate, iron oxide red (E172), magnesium stearate, talc.

Each LEXOTAN 6 tablet contains 6 mg bromazepam.

The other ingredients are: microcrystalline cellulose, lactose monohydrate, indigotine aluminium lake (E132), iron oxide yellow (E172), magnesium stearate, talc.

**WHAT LEXOTAN IS USED FOR**

LEXOTAN contains a medicine called bromazepam. This belongs to a group of medicines called benzodiazepines.

Initial: \_\_\_\_\_

G/2.6/86 &amp; G/2.6/87

Each tablet contains 3,0 mg bromazepam

Amended: 11 Oct 2019

Each tablet contains 6,0 mg bromazepam

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LEXOTAN is used for the treatment of severe anxiety (very strong fear or deep worry that can affect feelings, mood, behaviour and thinking patterns). Only a short course of treatment with LEXOTAN is recommended.

### **BEFORE TAKING LEXOTAN**

#### **Do not take LEXOTAN:**

- If you are allergic (hypersensitive) to bromazepam or to any other ingredients of LEXOTAN, or other medicines from the group of medicines known as benzodiazepines.
- If you suffer from myasthenia gravis (severe muscle weakness and tiredness).
- If you suffer from lung disease.
- If you suffer from breathing difficulties.
- If you suffer from a condition called 'sleep apnoea syndrome' (where your breathing stops when you are asleep).
- If you have severe liver disease.

**LEXOTAN must not be given to children.**

#### **Take special care with LEXOTAN:**

Tell your doctor if you:

- have a lung, liver or kidney condition.
- are being treated for depression or any other psychiatric illness.
- regularly drink alcohol or use recreational drugs.
- have had problems with alcohol or drug use in the past.

Benzodiazepines have a muscle relaxing effect so there is an increased risk of falls and consequent injury, especially if you are elderly.

### **Operations**

**Initial:** \_\_\_\_\_

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

**Taking LEXOTAN with food and drink:**

- **Do not drink alcohol while you are taking LEXOTAN.** Alcohol will increase the sedative effects of LEXOTAN.

**Pregnancy and Breastfeeding**

**Pregnancy:** Do not take LEXOTAN if you are pregnant or might become pregnant. If your doctor has decided that you should receive LEXOTAN during late pregnancy or during labour, your baby might have a low body temperature, floppiness and breathing difficulties, or your baby may develop withdrawal symptoms, if LEXOTAN is taken regularly in late pregnancy.

**Breastfeeding:** Bromazepam passes into breast milk therefore, if you are breastfeeding, you should not take LEXOTAN

If you are pregnant or breastfeeding your baby while taking LEXOTAN, please consult your doctor, pharmacist or other health care professional for advice.

**Driving and using machinery**

LEXOTAN may make you sleepy, affect your concentration and slow down your reactions. This may affect your performance at skilled tasks e.g. driving and operating machinery or tools.

**Important information about some of the ingredients of LEXOTAN:**

LEXOTAN contains lactose monohydrate, 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), talk to your doctor before taking this medicine.

**Taking other medicines with LEXOTAN:**

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If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of LEXOTAN with these medicines may cause undesirable interactions. Please consult your, doctor, pharmacist or other health care professional for advice.

Tell your doctor or pharmacist if you are taking any other medicines, including those not prescribed by your doctor. This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines involved.

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

- Medicines to treat mental health problems (e.g. antipsychotics; hypnotics, antidepressants).
- Medicines to help you sleep (e.g. anxiolytics or sedatives).
- Medicines for allergies (antihistamines), which make you sleepy.
- Medicines to treat epilepsy.
- Strong painkillers (such as morphine).
- Cimetidine (a medicine used to treat some stomach problems).

## HOW TO TAKE LEXOTAN

Always take LEXOTAN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Swallow the tablets whole with a little water or another non-alcoholic drink.

The dose your doctor prescribes will depend on the nature of your illness, your reaction to the medicine, your age and bodyweight. Your doctor will start you on an initial low dose and gradually increase it until the desired effect is achieved.

- For adults the dose is 1,5 – 3 mg three times a day.
- In hospitalised patients the dose may be increased to 6 -12 mg two or three times a day.
- After taking LEXOTAN, you should ensure that you have 7 to 8 hours uninterrupted sleep.
- If you are elderly, your doctor will prescribe half the dose normally recommended.
- You will also receive a lower dose than normal if you have liver and/or kidney condition.

Initial: \_\_\_\_\_

If you have the impression that the effect of LEXOTAN is too strong or too weak, talk to your doctor or pharmacist.

**If you take more LEXOTAN than you should:**

- If you take more LEXOTAN than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.
- If you take too many tablets, you will experience symptoms that will range from drowsiness, mental confusion, lethargy and in extreme cases have difficulty controlling your movements (lack of co-ordination), coma and death.

If someone else takes your LEXOTAN tablets by mistake, they should talk to a doctor or go to a hospital straight away.

**If you forget to take LEXOTAN:**

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

**Effects when treatment with LEXOTAN is stopped:**

**Stopping LEXOTAN**

Your doctor will advise you when to stop taking LEXOTAN. Please remember that it is not suitable for long-term use and that, after a couple of weeks, it is worth trying to get by without it, but talk to your doctor before changing your dose. This will help to prevent you becoming used to it and reduce the risk of dependence.

Treatment should be as short as possible. The overall duration of treatment should not usually be more than 8 -12 weeks, including a gradual tapering off process. Sometimes withdrawal effects occur when LEXOTAN is stopped, and particularly if it is stopped suddenly.

**Initial:** \_\_\_\_\_

These may include headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability. In severe cases you may experience changes in behaviour, pins and needles, an increased sensitivity to light, noise and touch, hallucinations or fits.

Also your original problem may return when your treatment is stopped, and you may be anxious, restless and have mood changes. This is less likely if your dose is gradually reduced towards the end of your treatment.

In the unusual case where patients have taken benzodiazepines for a long time, a longer period will be needed over which their dosage will be reduced. Special help may be needed. Your doctor will be able to discuss this with you.

**Do not share medicines prescribed for you with another person.**

**In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.**

### **POSSIBLE SIDE EFFECTS**

LEXOTAN can have side effects.

Side effects include drowsiness, fatigue, muscle weakness, a feeling of emptiness, reduced alertness, confusion, headache, dizziness and changes in vision. These effects are likely to occur at the start of treatment and usually disappear after a while.

In rare cases, changes in behaviour, including restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares and hallucinations may occur. If these symptoms occur, you must inform your doctor. He/she may want you to stop taking this medicine.

Other adverse effects are stomach upsets, skin rashes and changes in the level of sexual desire.

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If you are concerned about these or any other unexpected effect(s), talk to your doctor. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Not all side effects reported for LEXOTAN are included in this leaflet. Should your general health worsen while taking LEXOTAN, consult your doctor, pharmacist or other health care professional for advice.**

### **STORING AND DISPOSING OF LEXOTAN**

Keep this medicine out of the reach and sight of children.

Store LEXOTAN tablets below 30 °C.

Do not use LEXOTAN tablets after the expiry date (EXP) stated on the outer pack and label.

Do not throw away any left-over tablets. Instead, return them to your pharmacist so that they can be disposed of carefully. Only keep them if your doctor tells you to

### **PRESENTATION OF LEXOTAN**

LEXOTAN 3: Blister packs containing 30 or 90 tablets.

LEXOTAN 6: Blister packs containing 30 or 90 tablets.

### **IDENTIFICATION OF LEXOTAN**

LEXOTAN 3 tablets: Scored pale red, slightly speckled tablet, imprinted "Roche 3".

LEXOTAN 6 tablets: Scored pale green, slightly speckled tablet, imprinted "Roche 6".

### **REGISTRATION NUMBERS**

LEXOTAN 3: G/2.6/86

LEXOTAN 6: G/2.6/87

### **NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER**

Pharmaco Distribution (Pty) Ltd

3 Sandown Valley Crescent

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