Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

LAMODEX 5, 25, 50, 100, 200 mg dispersible/chewable tablets

Each tablet contains lamotrigine at a dosage of 5, 25, 50, 100 or 200 mg respectively.
Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

1. What is the medicine intended for?

Lamodex is intended for the treatment of epilepsy (Lamodex 5, 25, 50, 100, 200 mg dispersible/chewable tablets)
In adults and adolescents aged 13 years and above:
- **Lamodex** is given as monotherapy or in combination with other medicines, for the treatment of partial seizures and generalized seizures, including tonic-clonic seizures.
- Seizures that occur with Lennox-Gastaut syndrome. **Lamodex** is given as combination therapy with other medicines but may be used as the initial antiepileptic drug to start treatment in Lennox-Gastaut syndrome.

In children and adolescents aged 2 to 12 years:
- **Lamodex** is given as combination therapy with other medicines to treat unilateral seizures and generalized seizures, including tonic-clonic seizures and seizures occurring with Lennox-Gastaut syndrome.
- **Lamodex** is given as monotherapy for typical absence seizures.

Lamodex is intended for the treatment of bipolar disorder (Lamodex 25, 50, 100, 200 mg dispersible/chewable tablets).
In adults aged 18 years and above:
- **Lamodex** is given to prevent depressive episodes in patients suffering from bipolar I disorder who experience predominantly depressive episodes.

Lamodex is not intended for the acute treatment of depressive or manic episodes.

Therapeutic group: Lamodex belongs to a group of medicines called anticonvulsants.
Lamodex blocks the signals in the brain that trigger epileptic seizures.

2. Before using the medicine

Do not use the medicine if:

- **you are hypersensitive** (allergic) to the active ingredient (lamotrigine) or to any of the other ingredients this medicine contains (see section 6).

If this applies to you:
→ **Tell your doctor** and do not take **Lamodex**.

Special warnings regarding the use of the medicine
Before treatment with Lamodex, tell the doctor or pharmacist if:
- **you have any kidney problems.**
- **you have ever developed a rash** after taking lamotrigine or other medicines for bipolar disorder or epilepsy.
- **you have ever developed meningitis after taking lamotrigine** (read the description of these symptoms in section 4 of this leaflet: rare side effects).
- **you are already taking a medicine that contains lamotrigine.**
- **you suffer from a condition called Brugada syndrome.** Brugada syndrome is a genetic disease that causes abnormal electric activity within the heart. **Lamodex** may cause ECG abnormalities, which may lead to arrythmia (abnormal heart rhythm).

If one of these applies to you:
→ **Tell your doctor**, who may decide to lower the dosage or that **Lamodex** is not suitable for you.

Important information about potentially life-threatening reactions
A small number of people taking lamotrigine develop an allergic reaction or a potentially life-threatening skin reaction, which may develop into more serious problems if they are not treated. These can include Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). You need to recognize the symptoms to look out for while you are taking **Lamodex.**
→ **Read the description of these symptoms in section 4 of this leaflet** under "Potentially life-threatening reactions: seek medical help immediately**".**

Haemophagocytic lymphohistiocytosis (HLH)
There are reports of a rare but very serious immune system reaction in patients taking **Lamodex.**
→ **Contact your doctor or the pharmacist immediately**, if you experience one of the following symptoms while taking **Lamodex**: fever, rash, neurological symptoms (e.g., tremors, confusion, disturbances of brain function).

Thoughts of harming yourself or suicide
Anti-epileptic medicines are used to treat several conditions, including epilepsy and bipolar disorder**.** People with bipolar disorder can sometimes have thoughts of committing suicide or harming themselves. If you have bipolar disorder, you may be more likely to think like this:
- when you first start treatment or with a change in dosage
- if you have previously had thoughts about harming yourself or about suicide
- if you are under 25 years of age

If you have distressing thoughts or experiences, or if you notice that you feel worse or develop new symptoms while you are taking **Lamodex**:
→ **Refer to a doctor as soon as possible or go to the nearest hospital for help.**
You may find it helpful to tell a family member, caretaker or close friend that you can become depressed or have significant mood swings and ask them to read this leaflet. You can ask them to tell you if they are concerned about your depression or about other changes in your behavior.

A small number of people being treated with antiepileptics such as **Lamodex** have also had thoughts of harming themselves or suicide. If at any time you have such thoughts, **immediately contact your doctor.**

If you are taking Lamodex for epilepsy
The seizures in some types of epilepsy may occasionally become worse or happen more often while you are taking **Lamodex**. Some patients may experience severe seizures, which may cause serious health problems. If your seizures happen more often or if you experience a severe seizure while you are taking **Lamodex**:
→ **Refer to a doctor as soon as possible.**

Children and adolescents
Lamodex is not intended for children under two years of age.
Lamodex is not intended for people under 18 years of age to treat bipolar disorder. Medicines to treat depression and other mental health problems increase the risk of suicidal behavior and thoughts in children and adolescents aged under 18 years.

Drug interactions
If you are taking, or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Your doctor needs to know if you are taking other medicines for the treatment of epilepsy or mental health problems, to make sure you take the correct dosage of **Lamodex**. These medicines include:
- **Oxcarbazepine, felbamate, gabapentin, levetiracetam, pregabalin, topiramate** or **zonisamide**, used to treat **epilepsy.**
- **Lithium, olanzapine** or **aripiprazole** used to treat **mental health problems.**
- **Bupropion**, used to treat **mental health problems** or to **stop smoking.**
→ **Tell your doctor** if you are taking one of these.

Some medicines interact with **Lamodex** or make it more likely that people will have side effects**.**
These include:
- **Valproate**, used to treat **epilepsy** and **mental health problems**.
- **Carbamazepine**, used to treat **epilepsy** and **mental health problems**.
- **Phenytoin, primidone** or **phenobarbitone**, used to treat **epilepsy.**
- **Risperidone**, used to treat **mental health problems.**
- **Rifampicin**, which is an **antibiotic.**
- **Medicines** used to treat **Human Immunodeficiency Virus (HIV)** infection (a combination of lopinavir and ritonavir or atazanavir and ritonavir).
- **Hormonal contraceptives**, such as **contraceptive pills** (see below).

→ **Tell your doctor** if you are taking one of these or if you start or stop taking one of these.

Hormonal contraceptives (such as contraceptive pills) can affect the way Lamodex works
Your doctor may recommend that you use a particular type of hormonal contraceptive or another method of contraception such as condoms, a diaphragm, or an intrauterine device. If you are using a hormonal contraceptive such as contraceptive pills, your doctor may refer you to take blood tests to check the level of lamotrigine. If you are using a hormonal contraceptive or if you plan to start using one:
→ **Talk to your doctor**, who will discuss suitable methods of contraception with you.
Lamodex may also affect the way hormonal contraceptives work, although it is unlikely to make them less effective. If you are using a hormonal contraceptive and notice any changes in your menstrual pattern, such as breakthrough bleeding or spotting between periods:
→ **Tell your doctor.** These may be signs that **Lamodex** is affecting the way your contraceptive is working.

Use of this medicine and food
The medicine can be taken with or without food.

Your doctor may also advise you to start or stop taking other medicines, depending on what medical condition you are being treated for and the way you respond to treatment.
Lamodex tablets can be swallowed whole with a little water or chewed or mixed with water to make a liquid medicine.
To chew the tablet:
You may need to drink a little water while chewing the tablet to help the tablet dissolve in the mouth. Then drink a little more water to make sure all the medicine has been swallowed.
To make a liquid medicine:
- Put the tablet in a glass with enough water to cover the entire tablet.
- Either stir to dissolve or wait until the tablet is fully dissolved.
- Drink all the liquid.
- Add a little more water to the glass and drink it to make sure no medicine is left in the glass.

Lamodex 5 mg dispersible/chewable tablets: may be halved. **Lamodex** 25, 50, 100, 200 mg dispersible/chewable tablets: Do not halve the tablet since there is no score line.
There is no information on crushing the tablet.
If you have accidently taken a higher dosage
If you have taken an overdose or if a child has accidentally swallowed the medicine, **proceed immediately to a doctor or to the hospital emergency room**, and bring the package of the medicine with you.
If you take too much **Lamodex, there is a higher likelihood that you will develop serious side effects which may be fatal.**
Someone who has taken too much **Lamodex** may develop any of these symptoms:
- rapid, uncontrollable eye movements (nystagmus)
- clumsiness and lack of coordination, affecting balance (ataxia)
- heart rhythm changes (usually detected on ECG)
- loss of consciousness, fits (seizures) or coma

If you forgot to take a single dose of Lamodex
→ **In such a case, do not take extra tablets to make up for a forgotten dose. Take your next dose at the usual time.**
If you forgot to take several doses of Lamodex
→ **Ask your doctor for advice on how to start taking it again. It is important that you do this.**
Do not stop taking Lamodex without consultation
You must take **Lamodex** for as long as your doctor recommends. Do not stop unless your doctor advises you to.
If you are taking Lamodex to treat epilepsy
To stop taking **Lamodex**, it is important that the dosage **will** be reduced gradually over about two weeks. If you suddenly stop taking **Lamodex**, your epilepsy may come back or get worse.
If you are taking Lamodex to treat bipolar disorder
Lamodex may take some time to work, so you are unlikely to feel better immediately. If you stop taking **Lamodex**, there is no need to gradually reduce your dosage, but you should still talk to your doctor first if you want to stop taking **Lamodex.**
Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions on the use of the medicine, consult the doctor or a pharmacist.

4. Side effects

Like any medicine, the use of **Lamodex** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Potentially life-threatening reactions: seek medical help immediately
A small number of people taking lamotrigine develop an allergic reaction or potentially life-threatening skin reaction, which may develop into more serious problems if they are not treated.
These symptoms are more likely to occur during the first few months of treatment with **Lamodex**, especially if the starting dosage is too high or if the dosage is increased too quickly or if **Lamodex** is taken with another medicine called valproate. Some of the symptoms are more common in children, so parents should be especially careful to watch out for them.
Symptoms of these reactions include:
- **skin rashes or redness,** which may develop into life-threatening skin reactions including widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), extensive peeling of the skin (more than 30% of the body surface- toxic epidermal necrolysis) or extended rashes with liver, blood and other body organ involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as hypersensitivity syndrome DRESS)
- **ulcers in the mouth, throat, nose or genitals**
- **a sore mouth or red or swollen eyes** (conjunctivitis)
- **a high fever**, flu-like symptoms or drowsiness
- **swelling around your face** or **swollen glands** in your neck, armpit or groin
- **unexpected bruising or bleeding**, or the fingers turning blue
- **a sore throat** or more infections (such as colds) than usual
- increased levels of liver enzymes seen in blood tests
- an increase in a specific type of white blood cell (eosinophils)
- enlarged lymph nodes
- involvement of body organs including liver and kidneys

In many cases, these symptoms will be signs of less serious side effects **but you must be aware that they are potentially life-threatening and can develop into more serious problems**, such as organ failure, if they are not treated. If you notice any of these symptoms:
→ **Refer to a doctor immediately.** Your doctor may refer you to take tests on your liver, kidneys or blood and may tell you to stop taking **Lamodex**. In case you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis, your doctor will tell you that you must never take **Lamodex** again.

Haemophagocytic lymphohistiocytosis (HLH) (see in section 2 "Special warnings regarding the use of the medicine").

Very common side effects (effects that appear in more than 1 in 10 users):
- headache
- skin rash

Common side effects (effects that appear in 1-10 out of 100 users):
- aggression or irritability
- feeling sleepy or drowsy
- feeling dizzy
- tremors
- insomnia
- feeling agitated
- diarrhea
- dry mouth
- nausea or vomiting
- feeling tired
- pain in the back or joints, or elsewhere

Uncommon side effects (effects that appear in 1-10 out of 1,000 users):
- clumsiness and lack of coordination (ataxia)
- double vision or blurred vision
- unusual hair loss or thinning (alopecia)

Rare side effects (effects that appear in 1-10 out of 10,000 users):
- a life-threatening skin reaction (Stevens-Johnson syndrome) (see also the information at the beginning of section 4)
- a group of symptoms that appear together including: fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. This may be caused by an inflammation of the membranes that cover the brain and spinal cord (meningitis). These symptoms usually disappear once treatment is stopped, however, if the symptoms continue or get worse, **contact your doctor**
- rapid, uncontrollable eye movements (nystagmus)
- itchy eyes, with discharge and crusting of it on the eyelids (conjunctivitis)

Very rare side effects (effects that appear in less than 1 in 10,000 users):
- a life-threatening skin reaction (toxic epidermal necrolysis) (see also the information at the beginning of section 4)
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) (see also the information at the beginning of section 4)
- a high fever (see also the information at the beginning of section 4)
- swelling around the face (oedema) or swollen glands in the neck, armpit or groin (enlarged lymph nodes) (see also the information at the beginning of section 4)
- changes in liver function, which will show up in blood tests or liver failure and yellowing of the skin (see also the information at the beginning of section 4)
- a serious disorder of blood clotting, which can cause unexpected bleeding or bruising (disseminated intravascular coagulation) (see also the information at the beginning of section 4)
- Haemophagocytic lymphohistiocytosis (HLH) (see in section 2 "Special warnings regarding the use of the medicine")
- changes which may show up in blood tests - including reduced numbers of red blood cells (anaemia), reduced numbers of white blood cells (leucopenia, neutropenia, agranulocytosis), reduced numbers of platelets (thrombocytopenia), reduced numbers of all of these types of cell (pancytopenia) and a disorder of the bone marrow called aplastic anaemia
- hallucinations (seeing or hearing things that do not really exist)
- confusion
- feeling unbalanced or unsteady when you move
- uncontrollable body movements (tics), uncontrollable muscle spasms affecting the eyes, head and upper body (choreoathetosis) or other unusual body movements such as involuntary movements, shaking or stiffness
- in people who already have epilepsy, an increase in the frequency of the seizures
- in people who have Parkinson's disease, worsening of the symptoms
- lupus-like reaction (symptoms may include: back or joint pain which may sometimes be accompanied by fever and/or a general feeling of ill health)

Other side effects
Other side effects have occurred in a small number of users but their exact frequency is unknown:
- There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are being treated with long term anti-epileptic medication, have a history of osteoporosis or if you take steroids
- Kidney inflammation (tubulointerstitial nephritis) or inflammation of both kidney and eye (tubulointerstitial nephritis and uveitis syndrome)
- Nightmares
- A decrease in the effectiveness of the immune system, due to low blood levels of antibodies called immunoglobins which help protect against infections

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.
Side effects can be reported to the Ministry of Health via the link "דיווח על תופעת לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link:
https://sideeffects.health.gov.il

5. How to store the medicine

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store above 25°C.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Mannitol, crospovidone, acesulfame potassium, sodium stearyl fumarate, orange flavour, silica colloidal anhydrous.
What the medicine looks like and what the package contains:
Lamodex 5 mg dispersible/chewable tablets: Off-white tablets, round, biconvex, with a score line on one side.
Lamodex 25, 50, 100, 200 mg dispersible/chewable tablets: Off-white tablets, round, flat, with the dosage imprinted on one side.
Approved package sizes: 2, 7, 10, 14, 20, 28, 30, 56, 60, 100 dispersible/chewable tablets.
Not all package sizes may be marketed.
Revised in January 2021 according to MOH guidelines
Drug registration number at the national drug registry of the Ministry of Health:
Lamodex 5 mg dispersible/chewable tablets:
129-85-30811-00
Lamodex 25 mg dispersible/chewable tablets:
129-86-30812-00
Lamodex 50 mg dispersible/chewable tablets:
129-87-30813-00
Lamodex 100 mg dispersible/chewable tablets:
129-88-30814-00
Lamodex 200 mg dispersible/chewable tablets:
129-89-30815-00

Lamodex 5, 25, 50, 100, 200 mg disp chew tabs PIL PB0321-07

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