

PACKAGE LEAFLET: Information for the user

PROLAGIN

Tablets – 50 mg, 200 mg

(Lamotrigine)

Read all of this leaflet carefully before you start taking this medicine.

- 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. 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Prolagin is and what it is used for
2. What you need to know before you take Prolagin
3. How to take Prolagin
4. Possible side effects
5. How to store Prolagin
6. Other information

1. WHAT PROLAGIN IS AND WHAT IT IS USED FOR

Prolagin belongs to a group of medicines called *anti-epileptics*. It is used to treat two conditions – epilepsy and bipolar disorder.

Prolagin treats epilepsy by blocking the signals in the brain that trigger epileptic seizures (fits).

- For adults and children aged 13 years and over, Prolagin can be used on its own or with other medicines, to treat epilepsy. Prolagin can also be used with other medicines to treat seizures that occur with a condition called Lennox-Gastaut syndrome.
- For children aged between 2 and 12 years, Prolagin can be used with other medicines, to treat those conditions. It can be used on its own to treat a type of epilepsy called typical absence seizures.

Prolagin also treats bipolar disorder

People with bipolar disorder (sometimes called *maniacal depression*) have extreme mood swings, with periods of mania (excitement or euphoria) alternating with periods of depression (deep sadness or despair). For adults aged 18 years and over, Prolagin can be used on its own or with other medicines, to prevent the periods of depression that occur in bipolar disorder. It is not yet known how Prolagin works in the brain to have this effect.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PROLAGIN

Do not take Prolagin:

- if you are allergic to lamotrigine or to any of the excipients of this medicine (listed in section 6).

If this applies to you, tell your doctor, and don't take Prolagin.

Warnings and precautions

Talk to your doctor or pharmacist before taking Prolagin.

Your doctor needs to know before you take Prolagin:

- if you have any kidney problems
- if you have ever developed a rash after taking lamotrigine or other medicines for bipolar disorder or epilepsy; or if you experience a rash or sunburn after taking lamotrigine and having been exposed to sun or artificial light (e.g. solarium); your doctor will check your treatment and may advise you to avoid sunlight or protect yourself against the sun (e.g. use of a sunscreen and/or to wear protective clothing)
- if you ever developed meningitis after taking lamotrigine (read the description of these symptoms in Section 4, Rare side effects)
- if you are already taking medicines that contain lamotrigine
- if you have a condition called Brugada syndrome. Brugada syndrome is a genetic disease that results in abnormal electrical activity within the heart. ECG abnormalities which may lead to arrhythmias (abnormal heart rhythm) can be triggered by lamotrigine.

If any of these applies to you, **tell your doctor**, who may decide to lower the dose, or that Prolagin is not suitable for you.

Important information about potentially serious reactions

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis or Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)) have been reported with the use of lamotrigine, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.

Additional signs to look for include: ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).

These potentially life-threatening skin rashes are often accompanied by flu-like symptoms.

The rash may progress to widespread blistering or peeling of the skin.

DRESS appears initially as flu-like symptoms and a rash on the face, then with an extended rash with high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

The highest risk for occurrence of serious skin reactions is within the first weeks of treatment. If you have developed Stevens-Johnson syndrome, toxic epidermal necrolysis or DRESS with the use of Prolagin, you must not be re-started on Prolagin at any time.

If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell him that you are taking this medicine.

Haemophagocytic lymphohistiocytosis (HLH)

There have been reports of a rare but very serious immune system reaction in patients taking lamotrigine.

Contact your doctor or pharmacist immediately if you experience any of the following symptoms while taking lamotrigine: fever, rash, neurological symptoms (e.g. shaking or tremor, confusional state, 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 harming themselves or committing suicide. If you have bipolar disorder, you may be more likely to think like this:

- when you first start treatment
- if you have previously had thoughts about harming yourself or about suicide
- if you are under 25 years old.

Occasionally, people with epilepsy may also have thoughts of harming themselves or committing suicide. A small number of people being treated with lamotrigine for bipolar disorder or epilepsy have had these thoughts.

If you have distressing thoughts or experiences, or if you notice that you feel worse or develop new symptoms while you're taking Prolagin, see a doctor as soon as possible or go to the nearest hospital for help.

If you are taking Prolagin for epilepsy

The seizures in some types of epilepsy may occasionally become worse or happen more often while you are taking Prolagin. 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 Prolagin, see a doctor as soon as possible.

Prolagin should not be given to people aged under 18 years to treat bipolar disorder.

Medicines to treat depression and other mental health problems increase the risk of suicidal thoughts and behaviour in children and adolescents aged under 18 years.

Other medicines and Prolagin

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Your doctor needs to know if you are taking other medicines to treat epilepsy or mental health problems. This is to make sure you take the correct dose of Prolagin. 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 any of these.

Some medicines interact with Prolagin 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 the Pill (*see below*).

Tell your doctor if you are taking any of these, or if you start or stop taking any.

Hormonal contraceptives (such as the Pill) can affect the way Prolagin works

Your doctor may recommend that you use a particular type of hormonal contraceptive, or another method of contraception, such as condoms, a cap or a coil. If you are using a hormonal contraceptive like the Pill, your doctor may take samples of your blood 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. Prolagin can also affect the way hormonal contraceptives work, although it's unlikely to make them less effective. If you are using a hormonal contraceptive, and you notice any changes in your menstrual pattern, such as breakthrough bleeding or spotting between periods, tell your doctor. These may be signs that Prolagin is affecting the way your contraceptive is working.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not stop treatment without discussing this with your doctor. This is particularly important if you have epilepsy.

There may be an increased risk of birth defects in babies whose mothers took Prolagin during pregnancy. These defects include cleft lip or cleft palate. Your doctor may advise you to take extra folic acid if you are planning to become pregnant and while you are pregnant.

Pregnancy may also alter the effectiveness of Prolagin, so you may need blood tests and your dose of Prolagin may be adjusted.

Talk to your doctor if you're breastfeeding or planning to breastfeed.

The active ingredient of Prolagin passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breastfeeding while you are taking Prolagin, and will check your baby from time to time if you decide to breastfeed.

Driving and using machines

Prolagin can cause dizziness and double vision. Don't drive or operate machines unless you are sure you are not affected.

If you have epilepsy, talk to your doctor about driving and using machines.

Prolagin contains lactose

Prolagin tablets contain small amounts of a sugar called lactose. If you have an intolerance to lactose or any other sugars, tell your doctor, and don't take Prolagin.

3. HOW TO TAKE PROLAGIN

Always take this medicine exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

How much Prolagin to take

It may take a while to find the best dose of Prolagin for you. The dose you take will depend on:

- your age
- whether you are taking Prolagin with other medicines
- whether you have any kidney or liver problems.

Your doctor will prescribe a low dose to start, and gradually increase the dose over a few weeks until you reach a dose that works for you (called the *effective dose*). Never take more Prolagin than your doctor tells you to.

The usual effective dose of Prolagin for adults and children aged 13 years or over is between 100 mg and 400 mg each day.

For children aged 2 to 12 years, the effective dose depends on their body weight; usually, it is between 1 mg and 15 mg for each kilogram of the child's weight, up to a maximum of 400 mg daily.

How to take your dose of Prolagin

Take your dose of Prolagin once or twice a day, as your doctor advises. You can take it with or without food.

Your doctor may also advise you to start or stop taking other medicines, depending on what condition you are being treated for and the way you respond to treatment.

- Swallow your tablets whole. Don't break, chew or crush them.
- Always take the full dose that your doctor has prescribed. Never take only part of a tablet.

If you take more Prolagin than you should

Contact a doctor or pharmacist immediately. If possible, show them the Prolagin box.

Someone who has taken too much Prolagin may have any of these symptoms:

- rapid, uncontrollable eye movements (nystagmus)
- clumsiness and lack of co-ordination, affecting their balance (ataxia)
- heart rhythm changes (detected usually on ECG)
- loss of consciousness, convulsions or coma.

If you forget to take Prolagin

Do not take extra tablets or a double dose to make up for a forgotten dose.

Ask your doctor for advice on how to start taking it again. It's important that you do this.

Don't stop taking Prolagin without advice.

Prolagin must be taken for as long as your doctor recommends. Don't stop unless your doctor advises you to.

If you are taking Prolagin for epilepsy

To stop taking Prolagin it is important that your dose is reduced gradually, over about 2 weeks. If you suddenly stop taking Prolagin, your epilepsy may come back or get worse.

If you are taking Prolagin for bipolar disorder

Prolagin may take some time to work, so you are unlikely to feel better straight away. If you stop taking Prolagin, your dose will not need to be reduced gradually. But you should still talk to your doctor first, if you want to stop taking Prolagin.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Potentially serious allergic or skin reactions: get a doctor's help straight away.

A small number of people taking lamotrigine get an allergic reaction or potentially serious skin reaction which may develop into more serious problems, and even life-threatening if they are not treated.

These symptoms are more likely to happen during the first few months of treatment with lamotrigine, especially if the starting dose is too high or if the dose is increased too quickly, or if Prolargin 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 severe 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 Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
- ulcers in the mouth, throat, nose or genitals
- a sore mouth or red or swollen eyes (conjunctivitis)
- high temperature (fever), flu-like symptoms or drowsiness
- swelling around your face, or swollen glands in your neck, armpit or groin
- unexpected bleeding or bruising, 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 type of white blood cells (eosinophils)
- enlarged lymph nodes
- involvement of the organs of the body 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 serious and can develop into more serious problems, such as organ failure, if they are not treated. If you notice any of these symptoms, contact a doctor

immediately. Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking Prolagin.

Very common side effects (may affect more than 1 user in 10):

- headache
- skin rash.

Common side effects (affect 1 to 10 users in 100):

- aggression or irritability
- feeling sleepy or drowsy
- feeling dizzy
- shaking or tremors
- difficulty in sleeping (insomnia)
- feeling agitated
- diarrhoea
- dry mouth
- feeling sick (nausea) or being sick (vomiting)
- feeling tired
- pain in your back or joints, or elsewhere.

Uncommon side effects (affect up to 1 user in 100):

- clumsiness and lack of co-ordination (ataxia)
- double vision or blurred vision
- unusual hair loss or thinning (alopecia)
- skin rash or sunburn after exposure to sun or artificial light (photosensitivity).

Rare side effects (affect 1 to 10 users in 1,000):

- itchy eyes, with discharge and crusty eyelids (conjunctivitis)
- potentially life-threatening skin rashes (Stevens-Johnson syndrome) have been reported (see section 2)
- rapid, uncontrollable eye movements (nystagmus)
- a group of symptoms 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.**

Very rare side effects (affect 1 to 10 users in 10,000):

- hallucinations ('seeing' or 'hearing' things that aren't really there)
- confusion
- feeling 'wobbly' or unsteady when you move
- uncontrollable body movements (*tics*), uncontrollable muscle spasms affecting the eyes, head and torso (*choreoathetosis*), or other unusual body movements such as jerking, shaking or stiffness
- a potentially life-threatening skin rash (toxic epidermal necrolysis) has been reported (see section 2)
- in people who already have epilepsy, seizures happening more often
- changes in liver function, which will show up in blood tests, or liver failure
- changes which may show up in blood tests — including reduced number of red blood cells (*anaemia*), reduced number of white blood cells (*leucopenia, neutropenia, agranulocytosis*), reduced number of platelets (*thrombocytopenia*), reduced number of all these types of cells (*pancytopenia*), and a disorder of the bone marrow called *aplastic anaemia*
- a serious disorder of blood clotting, which can cause unexpected bleeding or bruising (*disseminated intravascular coagulation*)
- high temperature (*fever*)
- swelling around the face (*oedema*) or swollen glands in the neck, armpit or groin (*lymphadenopathy*)
- in people who already have Parkinson's disease, worsening of the symptoms
- DRESS
- haemophagocytic lymphohistiocytosis (HLH)
- Lupus-like reaction (symptoms may include: back or joint pain which sometimes may be accompanied by fever and/or general ill health).

Not known side effects (frequency cannot be estimated from the available data):

- 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 on long-term antiepileptic medication, have a history of osteoporosis, or take steroids

- nightmares
- inflammation of the kidney (tubulointerstitial nephritis), or inflammation of both the kidney and the eye (tubulointerstitial nephritis and uveitis syndrome)
- weakened immunity because of lower levels of antibodies called immunoglobulins in the blood which help against infection.

If you get side effects, if any of the side effects becomes severe or troublesome, or if you notice any side effects not listed in this leaflet, **please tell your doctor or pharmacist**.

5. HOW TO STORE PROLAGIN

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

Do not use this medicine after the expiry date which is stated on the blisters and carton.

6. OTHER INFORMATION

What Prolagin tablets contain

The active substance is lamotrigine.

Each tablet contains 50 mg or 200 mg lamotrigine.

The excipients are: lactose monohydrate, microcrystalline cellulose, povidone, iron oxide yellow, sodium starch glycolate, magnesium stearate, talc, silica colloidal anhydrous.

Contents of the pack

Prolagin 50 mg: box with 50 tablets

Prolagin 200 mg: box with 50 tablets.

Marketing Authorisation Holder and Manufacturer

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