**Package leaflet: Information for the patient**

**Lamotrigine Viatris 25 mg dispersible tablets**
**Lamotrigine Viatris 100 mg dispersible tablets**

**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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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

## 1. What Lamotrigine Viatris is and what it is used for

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

**Lamotrigine Viatris treats epilepsy** by blocking the signals in the brain that trigger epileptic seizures (fits):
- For adults and children aged 13 years and over, Lamotrigine Viatris can be used on its own or with other medicines, to treat epilepsy. Lamotrigine Viatris can also be used with other medicines to treat the seizures that occur with a condition called Lennox-Gastaut syndrome.
- For children aged between 2 and 12 years, Lamotrigine Viatris 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.

**Lamotrigine Viatris also treats bipolar disorder**.
People with bipolar disorder (sometimes called manic 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, Lamotrigine Viatris 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 Lamotrigine Viatris works in the brain to have this effect.

## 2. What you need to know before you take Lamotrigine Viatris

**Do not take Lamotrigine Viatris:**
- if you are **allergic** to lamotrigine or any of the other ingredients of this medicine (listed in section 6).

If this applies to you, **tell your doctor**, and do not take Lamotrigine Viatris.

**Warnings and precautions:**
Talk to your doctor or pharmacist before taking Lamotrigine Viatris if any of the following applies to you, who may decide to lower your dose or that Lamotrigine Viatris is not suitable for you:

- if you have problems with your kidneys
- if you have ever developed a rash when you have taken lamotrigine or other medicines for bipolar disorder or epilepsy
- if you have ever developed meningitis after taking lamotrigine (read the description of these symptoms in section 4 of this leaflet)
- if you are already taking medicine that contains lamotrigine
- 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 have a condition called Brugada syndrome, or other heart problems. 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.

**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).

**Important information about potentially life-threatening reactions**
A small number of people taking Lamotrigine Viatris get an allergic reaction or 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 know the symptoms to look out for while you are taking Lamotrigine Viatris. These include skin rashes or redness, ulcers in the mouth or throat, sore mouth or throat, red or swollen eyes, fever, swelling around your face, swollen glands, unexpected bleeding or bruising.

Read the description of these symptoms in section 4 of this leaflet under 'Potentially life-threatening reactions: get a doctor's help straight away'.

The risk of serious skin reactions may be associated with a variant in genes called HLA-B*1502 in people from Asian origin (mainly Han Chinese and Thai). If you have been tested previously and know you are carrying this genetic variant, discuss this with your doctor before taking Lamotrigine Viatris.

The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of lamotrigine, you must not be re-started on lamotrigine 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.

**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.

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

A small number of people being treated with anti-epileptics such as Lamotrigine Viatris have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

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

**Lamotrigine Viatris 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 Lamotrigine Viatris**
**Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines** including herbal medicines or other medicines bought without a prescription. **It is important to tell your doctor or pharmacist if you are taking any other medicines for epilepsy at the same time as lamotrigine if you are pregnant, think you may be pregnant, or are planning to have a baby (see also the information in Section 2 on pregnancy and breastfeeding).**

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 Lamotrigine Viatris. 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**
- **paracetamol**, used to treat **pain** and **fever**

**Tell your doctor** if you are taking any of these.

Some medicines interact with Lamotrigine Viatris or make it more likely that you 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)
- **oestrogen-containing products, including hormonal contraceptives, such as the Pill (see below) and hormone replacement therapy (HRT)**
- varenicline, used to stop smoking
- metformin used to treat diabetes

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 Lamotrigine Viatris 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 Viatris. If you are using or plan to start using a hormonal contraceptive, **talk to your doctor**, who will discuss suitable methods of contraception with you.

Lamotrigine Viatris can also affect the way hormonal contraceptives work, although it is 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 Lamotrigine Viatris is affecting the way your contraceptive is working.

**Pregnancy and breast-feeding**
**If you are pregnant or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the epilepsy medicine you are taking might pose to your unborn baby.**
**If you are planning to become pregnant you should discuss your epilepsy treatment with your doctor as early as possible before you become pregnant.**

- **You should not stop treatment without discussing this with your doctor.** This is particularly important if you have epilepsy.
- Pregnancy may alter the effectiveness of Lamotrigine Viatris, so you may need blood tests and your dose of Lamotrigine Viatris may be adjusted.
- There may be a small increased risk of birth defects, including a cleft lip or cleft palate, if Lamotrigine is taken during the first 3 months of pregnancy.The risk of physical birth abnormalities may increase when higher doses of epilepsy medicines are taken or more than one epilepsy medicine is used at the same time. Where possible, your doctor will consider using one epilepsy medicine at the lowest effective dose to control your epilepsy.
- Your doctor may advise you to take **folic acid** if you are planning to become pregnant and while you are pregnant.

Pregnancy may also alter the effectiveness of Lamotrigine Viatris, so your doctor may take samples of your blood to check the level of Lamotrigine Viatris, and may adjust your dose.

**Breast-feeding**
If you are breast-feeding or planning to breast-feed ask your doctor or pharmacist for advice before taking this medicine. The active ingredient of Lamotrigine Viatris passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breast feeding while you are taking Lamotrigine Viatris, and will check your baby from time to time, whether drowsiness, rash or poor weight gain occurs, if you decide to breast-feed. Inform your doctor if you observe any of these symptoms in your baby.

**Driving and using machines**
Lamotrigine Viatris can cause dizziness and double vision.
**Do not** drive or use machines unless you are sure you are not affected.
**If you have epilepsy, talk to your doctor about driving and using machines.**

Lamotrigine Viatris contains sulphite ammonium caramel (E150d). This may rarely cause severe allergic reactions, including swelling of the lips, face or tongue and swallowing or breathing problems.

This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially "sodium free".

## 3. How to take Lamotrigine Viatris

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

**How much Lamotrigine Viatris to take**
It may take a while to find the best dose of Lamotrigine Viatris for you. The dose you take will depend on:
- your age
- whether you are taking Lamotrigine Viatris with other medicines
- whether you have problems with your kidneys or liver.

Your doctor will start you on a low dose, 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 Lamotrigine Viatris than your doctor tells you to.**

The recommended dose of Lamotrigine Viatris for adults and adolescents aged 13 years or over is between 100 mg and 400 mg each day.

**Use in children:**
For children aged 2 to 12 years, the recommended dose depends on their body weight. The recommended dose is between 1 mg and 15 mg for each kilogram of the child's weight, up to a maximum maintenance dose of 200 mg daily.

Lamotrigine Viatris is not recommended for use in children below 2 years of age.

**How to take your dose of Lamotrigine Viatris**
Take your dose of Lamotrigine Viatris once or twice a day, as your doctor advises. You can take it with or without food.

**Always take the full dose** that your doctor has prescribed. Never take only part of a tablet.

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.

You can take the dispersible tablets by swallowing them whole with a little water, by chewing them, or by dissolving them in water Never take only part of the liquid.

**If you chew the tablet**
You may need to drink a little water at the same time to help the tablet dissolve in your mouth. Then drink some more water to make sure you have swallowed all the medicine.

**To make a liquid medicine**

- Put the tablet in a glass with at least enough water to cover the whole tablet.
- Either stir to dissolve, or wait for about a minute, until the tablet is fully dissolved.
- Drink all the liquid.
- Add a little more water to the glass and drink that, to make sure you have taken all the medicine.

**If you take more Lamotrigine Viatris than you should**
**Contact a doctor or nearest hospital emergency department immediately.** If possible, show them the Lamotrigine Viatris packet.

**If you take too much Lamotrigine Viatris you may be more likely to have serious side effects which may be fatal**. Someone who has taken too much Lamotrigine Viatris 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, fits (convulsions) or coma.

**If you forget to take Lamotrigine Viatris - Do not take extra tablets or a double dose to make up for a forgotten dose.** Just take your next dose at the usual time. Ask your doctor for advice on how to start taking it again. It is important that you do this.

**Do not stop taking Lamotrigine Viatris without advice -** Take Lamotrigine Viatris for as long as your doctor recommends. Do not stop unless your doctor advises you to.

**If you are taking Lamotrigine Viatris for epilepsy,** it is important that your dose is reduced gradually, over about 2 weeks. If you suddenly stop taking Lamotrigine Viatris, your epilepsy may come back or get worse.

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

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

## 4. Possible side effects

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

**Potentially life-threatening reactions: get a doctor's help straight away**
A small number of people taking Lamotrigine Viatris get 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 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 Lamotrigine Viatris 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 rash with target lesions (Erythema multiforme), 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 organs involvement (DRESS)
- **Ulcers in the mouth, throat, nose or genitals**
- **A sore mouth or red or swollen eyes** (conjunctivitis)
- **A 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 your 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
- 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.

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. **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 Lamotrigine Viatris. In case you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis your doctor will tell you that you must never use lamotrigine again.

**Haemophagocytic lymphohistiocytosis (HLH)** (see section 2 What you need to know before you take Lamotrigine Viatris).
Lower immunity because of lower levels of antibodies called immunoglobulins in the blood which help protect against infection.

**Other side effects include:**

**Very common** (may affect more than 1 in 10 people):
- Headache
- Skin rash.

**Common** (may affect up to 1 in 10 people):
- Agitation, aggression or irritability
- Shaking or tremors
- Feeling dizzy
- Feeling sleepy, drowsy or tired
- Difficulty in sleeping
- Feeling sick (nausea) or being sick (vomiting)
- Diarrhoea
- Dry mouth
- Pain in your back or joints, or elsewhere.

**Uncommon** (may affect up to 1 in 100 people):
- Clumsiness and lack of co-ordination (ataxia)
- Double or blurred vision
- Hair loss
- Skin rash or sunburn after exposure to sun or artificial light (photosensitivity).

**Rare** (may affect up to 1 in 1,000 people):
- Skin reaction that causes red spots or patches on the skin, that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (erythema multiforme)
- A life-threatening skin reaction (Stevens-Johnson syndrome): (see also the information at the beginning of Section 4)
- 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**
- Rapid, uncontrollable eye movements (nystagmus)
- Itchy eyes, with discharge and crusty eyelids (conjunctivitis)

**Very rare** (may affect up to 1 in 10,000 people):
- Hallucinations ('seeing' or 'hearing' things that aren't really there)
- Confusion
- Feeling 'wobbly' or unsteady when you move about
- Uncontrollable repeated body movements and/or sounds or words (tics), uncontrollable muscle spasms affecting the eyes, head and torso (choreoathetosis), or other unusual body movements such as jerking, shaking or stiffness
- 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 numbers of red blood cells (anaemia), reduced numbers of white blood cells (leucopenia, neutropenia, agranulocytosis), reduced numbers of platelets (thrombocytopenia), reduced numbers 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)
- A high temperature (fever)
- In people who already have Parkinson's disease, worsening of the symptoms
- Lupus-like reaction (symptoms may include: back or joint pain which sometimes may be accompanied by fever and/or general ill health)
- DRESS (see 'Potentially life-threatening reactions' above)
- A life-threatening skin reaction (toxic epidermal necrolysis): (see also the information at the beginning of Section 4)
- Swelling around the face (oedema) or swollen glands in the neck, armpit or groin (lymphadenopathy): (see also the information at the beginning of Section 4)
- Haemophagocytic lymphohistiocytosis (HLH) (see Section 2: What you need to know before you take Lamotrigine Viatris).

**Other side effects** (Other side effects have occurred in a small number of people 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 on long-term antiepileptic medication, have a history of osteoporosis, or take steroids
- Swollen glands in the neck, armpit or groin (lymphadenopathy)
- Inflammation of the kidney (tubulointerstitial nephritis), or inflammation of both the kidney and the eye (tubulointerstitial nephritis and uveitis syndrome)
- Nightmares
- Lower immunity because of lower levels of antibodies called immunoglobulins in the blood which help protect against infection
- red nodules or patches on the skin (pseudolymphoma).

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Lamotrigine Viatris

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 carton and the blister after 'EXP'.
The expiry date refers to the last day of that month.
This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or 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 Lamotrigine Viatris contains**
The active substance is lamotrigine.
Lamotrigine Viatris 25 mg dispersible tablets: each tablet contains 25 mg lamotrigine.
Lamotrigine Viatris 100 mg dispersible tablets: each tablet contains 100 mg lamotrigine.

The other ingredients are magnesium stearate (E572), microcrystalline cellulose (E460), sodium starch glycolate, povidone, colloidal silica anhydrous (E551), saccharin sodium (E421), mannitol (E421) and blackcurrant flavouring containing glyceryl triacetate (E1518) and sulfite ammonia caramel (E150d) (see section 2 “Lamotrigine Viatris contains sulphite ammonium caramel (E150d)”.

**What Lamotrigine Viatris looks like and contents of the pack -**
Lamotrigine Viatris 25 mg dispersible tablets - White to off white, round tablets marked with 'LY' over '25' on one side and plain on the other side.
Lamotrigine Viatris 100 mg dispersible tablets – White to off white, round tablets marked with 'LY' over '100' on one side and plain on the other side.
The tablets are available in blisters of 14, 21, 28, 30, 46, 56, and 100 tablets.
Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
Viatris,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

**Manufacturers**
Mylan Hungary Kft, Mylan utca 1, Komarom 2900, Hungary.

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