

Lamictal® Tablets

lamotrigine

Please read this leaflet carefully before taking this medicine or giving it to someone you are looking after. It contains important information about the treatment. If you have any doubts or questions, or you are not sure about anything, ask your doctor or pharmacist.

What is in your medicine?

The name of your medicine is Lamictal Tablets. The active ingredient is lamotrigine. All tablets are pale yellow, are a rounded-square shape and contain either 25 mg, 50 mg, 100 mg or 200 mg of lamotrigine respectively.

Lamictal Tablets also contain the following as inactive ingredients: lactose; microcrystalline cellulose; sodium starch glycolate; povidone; magnesium stearate and iron oxide yellow.

Lamictal Tablets come in packs of 56 tablets.

Who makes Lamictal Tablets?

Lamictal Tablets are made by GlaxoSmithKline Pharmaceuticals S.A., Ul Grunwaldzka 189, 60-322 Poznań, Poland.

GlaxoSmithKline UK, Stockley Park West, Uxbridge, Middlesex UB11 1BT is licensed to sell Lamictal Tablets in the UK.

What are Lamictal Tablets for?

Lamictal belongs to a group of medicines called anticonvulsants.

It is used to treat various types of epilepsy in adults and children.

Lamictal may be used on its own to treat adults and children over 12 years.

Lamictal can also be used in combination with other anti-epileptic medicines in both adults and children aged 2 years and over.

Who can take Lamictal Tablets?

This medicine suits most people, but there are a few who should not take it, or who need to ask their doctor before doing so. Ask yourself these questions to check whether Lamictal Tablets are right for you:

- are you pregnant, trying to become pregnant or breast-feeding?
- have you previously had an allergic reaction to Lamictal, lamotrigine or any of the other ingredients in Lamictal Tablets listed above?
- have you ever had a rash during previous treatment with lamotrigine or with any other antiepileptic drug?
- are you taking any other medicines?
- are you taking any form of hormonal contraceptive (e.g. "the pill")? See "Taking Lamictal Tablets and Contraceptives" for more information.
- are you taking hormone replacement therapy (HRT)?
- are you taking valproate, carbamazepine, phenytoin, phenobarbital, primidone, rifampicin, olanzapine or oxcarbazepine?
- do you have liver or kidney disease?
- do you suffer from Parkinson's disease?

If the answer is **yes** to any of these questions (or if you are unsure if they apply) and if these points have not already been discussed with a doctor, tell your doctor or pharmacist **before** you take Lamictal Tablets.

Taking Lamictal Tablets and Contraceptives: If you are a woman who is starting treatment with Lamictal and you are already using a hormonal contraceptive (e.g. "the pill"), the method of contraception you use should be reviewed by your doctor. This is because non-hormonal methods of contraception should be used, and a hormonal contraceptive (e.g. "the pill") should only be used as the sole method of contraception if there is no other alternative. If you are already taking Lamictal and intend to start or stop taking hormonal contraceptives (e.g. "the pill"), you should discuss this with your doctor, who may need to change your dose of Lamictal. Lamictal may reduce the ability of hormonal contraceptives (e.g. "the pill") to work. Although not always seen, if you have any changes in menstrual pattern (e.g. break-through bleeding or spotting) contact your doctor as soon as possible, as this may be a sign of reduced effectiveness of hormonal contraceptives (e.g. "the pill").

Pregnancy: If you take Lamictal there could be an increased risk of birth defects, especially if you take other medication for your epilepsy in conjunction with Lamictal. It is important that you don't suddenly stop taking your medication so please speak with your doctor if you are pregnant or trying to become pregnant.

How do you take Lamictal Tablets?

Please note: Your doctor may give you different instructions to those written below.

It is important to take your medicine in the way your doctor has told you to, if you are unsure always check with your doctor. The dose your doctor will prescribe for you depends on whether you are taking any other medicines and if so which ones. This is especially important if you are taking any medicine containing valproate.

The pharmacist's label on your pack should tell you how many tablets to take and how often to take them. If the label doesn't say, or if you are not sure, ask your doctor or pharmacist.

Adults and children over 12 years old: The usual dose used to control epilepsy is between 100 mg and 400 mg, taken once daily or in two divided doses. When you first start taking Lamictal, your doctor will prescribe a **much lower dose** than this and will then increase your dose gradually over a few weeks.

Children between 2 and 12 years of age: The usual dose used to control epilepsy is between 1 mg and 15 mg per kilogram of your child's body weight, taken once daily or in two divided doses. When your child first starts taking Lamictal, your doctor will prescribe a **much lower dose** than this for your child and will then increase it gradually over a few weeks.

Lamictal is not recommended for use in children under 2 years of age.

Lamictal is available in 2 mg and 5 mg strength dispersible tablets, which may be more suitable for doses used to treat younger children. The 2 mg dispersible tablet is currently the lowest strength available and Lamictal should not be administered if the required dose is less than 1 mg.

If you or your child has liver disease your doctor may prescribe less than the recommended dose, depending on how severe the liver condition is.

Swallow Lamictal Tablets with a little water.

If you forget to take a dose take another as soon as you remember and then go on as before.

If you take too much Lamictal, or if someone else takes your medicine by mistake, contact your doctor or nearest casualty department immediately.

Do not stop taking your medicine suddenly. Always ask your doctor first.

Do Lamictal Tablets have any side effects?

Along with its needed effects, a medicine may cause unwanted effects. Most people taking this medicine find it causes no problems. If any of the following symptoms occur, it is important to tell your doctor **immediately**, as more serious problems may result if left ignored. Some of these reactions are known to be more common in children, so parents should be especially aware of this:

- an unexpected skin reaction, e.g. a rash and/or a sore mouth or eyes
- swelling around the face
- if you get a high temperature, 'flu-like' symptoms, swollen glands or drowsiness, or if your epilepsy gets worse, particularly during the first month's treatment with Lamictal
- if you start feeling very tired, if you get any unexpected bruising or bleeding, if you start getting more infections (e.g. colds) than usual, or if you develop a sore throat.

Tell your doctor **as soon as possible** if you notice any of the following effects:

- blurred vision, redness of the eye (conjunctivitis), dizziness, headache, difficulty sleeping, feeling or being sick, diarrhoea, hallucinations, feeling irritable, aggressive, agitated or confused, pain (including back and joint pain)
- unsteadiness or loss of co-ordination when you walk
- if you have Parkinson's disease, any worsening of your symptoms such as shaking of the arms or legs, rolling of the eyes or a chewing movement of the mouth
- unusual movements that you can't control such as irregular jerking or shaking of the arms or legs
- if your seizures become more frequent.

There have been rare reports of abnormalities in liver function. If you have one or more of the following symptoms, which may or may not be accompanied by feeling sick and generally unwell, tell your doctor immediately:

- yellowing of the skin
- itching
- abdominal pain and/or tenderness.

Tell your doctor or pharmacist if you notice any other side effects from your medicine, which are not mentioned here.

Looking after your Lamictal Tablets

Keep your tablets in a dry, safe place where children cannot see or reach them. They should be stored below 30°C.

Do not take any tablets after the end of the month shown on the pack.

If your doctor tells you to stop taking the tablets, please return any which are left over to your pharmacist. Only keep them if your doctor tells you to.

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Note: If you have any other questions about epilepsy, contact a doctor or pharmacist. Alternatively, the British Epilepsy Association will be happy to try and answer them for you. You can telephone their National Information Centre free from anywhere in the country on 0808 8005050 or write to them at New Anstey House, Gate Way Drive, Yeadon, Leeds LS19 7XY.

The information in this leaflet applies only to Lamictal Tablets.

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