

PATIENT INFORMATION LEAFLET

DYNA-LAMOTRIGINE RANGE

SCHEDULING STATUS:

S3

PROPRIETARY NAME AND DOSAGE FORM

DYNA-LAMOTRIGINE 25 mg, tablets

DYNA-LAMOTRIGINE 50 mg, tablets

DYNA-LAMOTRIGINE 100 mg, tablets

DYNA-LAMOTRIGINE 200 mg, tablets

Read all of this leaflet carefully before you start taking DYNA-LAMOTRIGINE tablets.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **DYNA-LAMOTRIGINE** 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.

1. WHAT DYNA-LAMOTRIGINE CONTAINS:

The active substance is lamotrigine.

The other ingredients are ethanol absolute, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, sodium starch glycolate.

DYNA-LAMOTRIGINE contains sugar (lactose monohydrate) in the following quantities;

DYNA-LAMOTRIGINE 25 mg (24,70 mg)

DYNA-LAMOTRIGINE 50 mg (49,40 mg)

DYNA-LAMOTRIGINE 100 mg (98,80 mg)

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DYNA-LAMOTRIGINE 200 mg (197,60 mg)

2. WHAT DYNA-LAMOTRIGINE IS USED FOR:

- **DYNA-LAMOTRIGINE** tablets are used to treat various types of epilepsy, including seizures associated with Lennox-Gastaut syndrome.
- **DYNA-LAMOTRIGINE** tablets are used to treat bipolar disorder (manic depression), specifically the periods of depression that occur in bipolar disorder.

3. BEFORE YOU TAKE DYNA-LAMOTRIGINE:

Do not take DYNA-LAMOTRIGINE:

- if you are hypersensitive (allergic) to lamotrigine or any of the other ingredients of **DYNA-LAMOTRIGINE** (see **WHAT DYNA-LAMOTRIGINE CONTAINS**).

Take special care with DYNA-LAMOTRIGINE:

- tell your doctor immediately if you develop a skin rash or any other signs or symptoms of hypersensitivity e.g. fever, swollen face, flu-like symptoms, pain, tenderness or unusual swelling over the liver area in the upper belly, swollen lymph nodes, yellow skin or eyes, unusual bleeding, or nervous system conditions such as seizures, trouble walking, difficulty seeing or other visual disturbances. Your doctor will use a physical examination, blood tests and other evaluations to determine if you have developed hemophagocytic lymphohistiocytosis (HLH), a very serious immune system reaction, to **DYNA-LAMOTRIGINE**
- if you have thoughts of harming yourself or suicide
- tell your doctor if you are starting or stopping hormonal contraceptives, such as the Pill
- do not stop taking your tablets abruptly.

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Taking DYNA-LAMOTRIGINE with food and drink:

Avoid the use of alcohol. Food does not affect **DYNA-LAMOTRIGINE**'s function.

Pregnancy and breastfeeding:

Safety in pregnancy and breastfeeding has not been established, therefore do not take **DYNA-LAMOTRIGINE** if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking **DYNA-LAMOTRIGINE**.

Driving and using machinery:

DYNA-LAMOTRIGINE may make you dizzy and cause double vision. You should wait and see how **DYNA-LAMOTRIGINE** affects you before attempting to drive or operate machines.

Important information about some of the ingredients of DYNA-LAMOTRIGINE:

DYNA-LAMOTRIGINE contains lactose. Patients with the rare hereditary conditions of lactose intolerance should not take **DYNA-LAMOTRIGINE**.

DYNA-LAMOTRIGINE contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with DYNA-LAMOTRIGINE:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

It is especially important to tell your healthcare provider if you are taking any of the following medicines:

- other anti-epileptic medicines (phenytoin, carbamazepine, phenobarbitone and primidone)

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- antibiotics (rifampicin)
- HIV treatment (lopinavir/ritonavir and atazanavir/ritonavir)
- valproic acid, used in the treatment of epilepsy (fits)
- oral contraceptive tablets, such as the Pill (for example, ethinylloestradiol and levonorgestrel).

4. HOW TO TAKE DYNA-LAMOTRIGINE:

Do not share medicines prescribed for you with any other person.

Always take **DYNA-LAMOTRIGINE** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will prescribe a low dose to start and gradually increase the dose until you reach a dose that works for you.

Swallow the tablets with a little water.

Your doctor will tell you how long your treatment with **DYNA-LAMOTRIGINE** will last. Do not stop taking your tablets suddenly. Your doctor will tell you how to stop the therapy.

If you have the impression that the effect of **DYNA-LAMOTRIGINE** is too strong or too weak, tell your doctor or pharmacist.

If you take more DYNA-LAMOTRIGINE than you should:

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

Signs and symptoms of overdose include rapid, involuntary eye movement, loss of full control of bodily movements, loss of awareness, violent muscle contractions.

If you forget to take a dose of DYNA-LAMOTRIGINE:

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Do not take a double dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time. If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

5. POSSIBLE SIDE EFFECTS:

DYNA-LAMOTRIGINE can have side effects.

Not all side effects reported for **DYNA-LAMOTRIGINE** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking **DYNA-LAMOTRIGINE**, please consult your healthcare provider for advice.

If any of the following happens, stop taking **DYNA-LAMOTRIGINE** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- symptoms of hemophagocytic lymphohistiocytosis (HLH), an immune system reaction, characterised by fever, multi organ failure, pain, tenderness or unusual swelling over the liver area in the upper belly, swollen lymph nodes, skin rash, yellow skin or eyes, unusual bleeding or, nervous system conditions such as seizures, trouble walking, difficulty seeing, or other visual disturbances
- angioedema (trouble breathing, swelling of face, mouth, hands or feet).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **DYNA-LAMOTRIGINE**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- blood disorders (characterised by pale skin colour, weakness, frequent infections, generally feel unwell)

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- multiple bleeding sites, bruises, fever
- pancytopenia (characterised by infections, bleeding problems, rapid heart rate, pale skin)
- septic shock (characterised by high or very low temperature, chills, dizziness when standing, palpitations)
- increased seizures (fits)
- non-bacterial meningitis (characterised by fever, chills, headaches, vomiting, loss of appetite)
- liver problems (characterised by nausea, loss of appetite, fatigue, diarrhoea, yellowing of the skin or eyes)
- Stevens-Johnson syndrome (serious illness with blistering of the skin, mouth, eyes and genitals, skin rash).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- aggression, irritability, confusion
- headache, inability to sleep, dizziness, drowsiness, tremor, agitation
- paraesthesia (prickling, tingling, itching, burning or coldness of skin), ataxia (lack of control of bodily movements)
- vision problems including blurred or double vision, rapid involuntary eye movements
- feeling sick (nausea) or being sick (vomiting)
- severe skin rashes
- joint pain, muscle pain and weakness
- weight loss, tiredness, back pain, dryness of mouth.

Less frequent side effects:

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- lymph node disorder (you may experience fever or night sweats, more tiredness than usual, a painful, warm or red lump under your skin)
- hallucinations, tics (spasms in the face)
- anxiety, depression, forgetfulness, agitation, slurred speech
- pink-eye (conjunctivitis)
- rhinitis (stuffy, runny nose, sneezing), heartburn, temporary failure to breathe when sleeping
- constipation, diarrhoea, indigestion
- skin rash, hair loss
- fever, general discomfort/ illness (malaise), extreme sensitivity to light, flu-like symptoms.

Side effects with unknown frequency:

- nightmares
- dry cough
- bone fractures, delayed growth or development (occurs with long-term treatment).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF DYNA-LAMOTRIGINE:

Store at or below 25 °C in original pack.

Protect against moisture and light.

Do not remove the blister from the outer carton until required for use.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).