

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:****S3****PROPRIETARY NAME AND DOSAGE FORM****DYNA-LAMOTRIGINE 25 mg**, tablets (Lamotrigine 25 mg per tablet)**DYNA-LAMOTRIGINE 50 mg**, tablets (Lamotrigine 50 mg per tablet)**DYNA-LAMOTRIGINE 100 mg**, tablets (Lamotrigine 100 mg per tablet)**DYNA-LAMOTRIGINE 200 mg**, tablets (Lamotrigine 200 mg per tablet)

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)

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.

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**
- if you are 65 years or older
- if you have renal or hepatic impairment
- if you are pregnant or breastfeeding.

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**

- tell your doctor if you are starting or stopping hormonal contraceptives, such as the Pill
- do not stop taking your tablets abruptly.

Taking DYNA-LAMOTRIGINE with food and drink:

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

Pregnancy and breastfeeding:

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

Safety in pregnancy and breastfeeding has not been established.

Driving and using machinery:

Caution is advised when operating machinery and driving since **DYNA-LAMOTRIGINE** can cause blurred or double vision, dizziness, drowsiness and impairment of motor skills.

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.

Using other medicines with DYNA-LAMOTRIGINE:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **DYNA-LAMOTRIGINE** with these medicines may cause undesirable interactions.

Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

DYNA-LAMOTRIGINE interacts with the following medication:

- other anti-epileptic medicines (phenytoin, carbamazepine, phenobarbitone and primidone)
- pain killers (paracetamol)
- oral contraceptive tablet.

4. HOW TO USE DYNA-LAMOTRIGINE:

Always take **DYNA-LAMOTRIGINE** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **DYNA-LAMOTRIGINE** is too strong or too weak, talk to your doctor or pharmacist.

The usual dose is one to two tablets once or twice a day, but you may be told to take a lower dose for the first 2 – 4 weeks.

Swallow the tablets with a little water.

Do not stop taking your tablets suddenly. Your doctor will tell you how to stop the therapy.

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.

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

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.

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.

You may experience skin reaction such as skin rash, blistering, peeling and loosening of the skin

Muscle cramps, pain, weakness, red or irritated eyes, headache, dizziness, drowsiness and coordination abnormalities, vision.

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).