Please read this leaflet carefully before you start to receive your medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

LAMOTRIGINE NORMON 25 mg DISPERSIBLE TABLETS
LAMOTRIGINE NORMON 50 mg DISPERSIBLE TABLETS
LAMOTRIGINE NORMON 100 mg DISPERSIBLE TABLETS
LAMOTRIGINE NORMON 200 mg DISPERSIBLE TABLETS

The active substance is lamotrigine.
LAMOTRIGINE NORMON 25 mg DISPERSIBLE TABLETS: Each tablet contains 25 mg of lamotrigine.
LAMOTRIGINE NORMON 50 mg DISPERSIBLE TABLETS: Each tablet contains 50 mg of lamotrigine.
LAMOTRIGINE NORMON 100 mg DISPERSIBLE TABLETS: Each tablet contains 100 mg of lamotrigine.
LAMOTRIGINE NORMON 200 mg DISPERSIBLE TABLETS: Each tablet contains 200 mg of lamotrigine.

The others components (excipients) are: crospovidone, sodium saccharin, orange essence, magnesium stearate, and coloidal silica.

MARKETING AUTHORIZATION HOLDER AND MANUFACTURER
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1. WHAT LAMOTRIGINE NORMON DISPERSIBLE TABLETS IS AND WHAT IT IS USED FOR

LAMOTRIGINE NORMON comes in the form of dispersible tablets.

Each package of LAMOTRIGINE NORMON 25 mg DISPERSIBLE TABLETS contains 21, 42 or 56 tablets. Each package of LAMOTRIGINE NORMON 50 mg DISPERSIBLE TABLETS contains 42 or 56 tablets. Each package of LAMOTRIGINE NORMON 100 mg DISPERSIBLE TABLETS contains 56 tablets. Each package of LAMOTRIGINE NORMON 200 mg DISPERSIBLE TABLETS contains 30 tablets.

Lamotrigine belongs to a group of drugs known as antiepileptics.

It can be used to treat two types of disease: epilepsy and bipolar disorder or manic-depressive disease.

EPILEPSY: it is used for the treatment of different types of epilepsy, both alone (monotherapy) in adults or children over 12 years of age, or in combination with other drugs (adjunctive therapy) in adults or children aged 2 years or over.

BIPOLAR DISORDER: lamotrigine is used in adult patients with bipolar disorder to prevent the appearance of episodes of depression.

2. BEFORE TAKING LAMOTRIGINE NORMON DISPERSIBLE TABLETS

• Do not take LAMOTRIGINE NORMON DISPERSIBLE TABLETS if:
You have previously had an allergic reaction to lamotrigine or any of the other components of this drug.

• Take special care with LAMOTRIGINE NORMON DISPERSIBLE TABLETS:
- If on starting or during treatment you suffer any sort of skin reaction, either isolated or accompanied by fever, adenopathies (inflammation of the lymph glands) etc. In such cases, you should inform your doctor immediately as it may be necessary to stop the treatment. Lamotrigine can produce cutaneous reactions that are more frequent during the first 8 weeks of treatment, if high initial doses are received, if administered simultaneously with a drug called valproate or in the case of children. In the latter, such reactions may be confused with typical infant infection, as fever may also appear.
- If you suffer from liver or kidney disease, as a lower dose than normal may be required.
- If you are simultaneously taking a drug called carbamazepine, given that symptoms such as vertigo, gait alterations, visual alterations and nausea may appear that require a reduction in the dose of carbamazepine.
- If you have Parkinson's disease, as the symptoms may worsen.
- If you start or stop treatment with oral contraceptives or other feminine hormone preparations. Inform your doctor, as it may be necessary to adjust the LAMOTRIGINE NORMON maintenance dose.

• Pregnancy:
Consult your doctor or pharmacist before using any medicinal product.

Administration of LAMOTRIGINE NORMON can be associated with a reduction in folic acid that can affect the development of the foetus.

• Breastfeeding:
Consult your doctor or pharmacist before using any medicinal product.

As lamotrigine is excreted in breast milk, mothers are advised to feed their children with artificial food.

• Driving and operating machinery:
During treatment with LAMOTRIGINE NORMON, symptoms such as vertigo or visual alterations can appear that may affect your capacity to drive or use machinery. Always consult your doctor and observe whether the administration of lamotrigine affects you before driving or using machinery.

• Use of other drugs:
Inform your doctor or pharmacist if you are using or have recently used any other medicinal product, even if acquired without prescription, as it may be necessary to stop the treatment or adjust the dose of some of the drugs.

Simultaneous administration of hormonal contraceptives requires an increase in the dose of LAMOTRIGINE NORMON. If you are taking oral contraceptives, tell your doctor of any alterations to menstruation.

Simultaneous administration of antiepileptic drugs (phenytoin, carbamazepine, phenobarbital, valproate and primidone) and the antibiotic rifampicin may require an increase in the dose of lamotrigine, while joint administration with valproate requires a decrease in the lamotrigine dose. If you are already taking carbamazepine, starting treatment with lamotrigine may produce symptoms such as difficulty in maintaining balance or blurred vision, which generally clear up by reducing the carbamazepine dose.

3. HOW TO TAKE LAMOTRIGINE NORMON DISPERSIBLE TABLETS

Follow these instructions unless your doctor has indicated otherwise.

Your doctor will tell you how long your treatment should last.

The recommended dose depends on whether you are taking other antiepileptic drugs and, if so, which ones. This is particularly important if you are taking a drug that contains valproate (see the section Take special care with LAMOTRIGINE NORMON DISPERSIBLE TABLETS).

Remember to take your medicine.

LAMOTRIGINE NORMON dispersible tablets can be swallowed whole with a small amount of water. They may be chewed or dissolved in a small amount of water, sufficient to completely cover the tablet.

EPILEPSY:

The initial dose of LAMOTRIGINE NORMON DISPERSIBLE TABLETS varies according to whether the treatment is monotherapy (treatment with LAMOTRIGINE NORMON alone) or adjunctive therapy (if you are receiving treatment with LAMOTRIGINE NORMON and valproate or other drugs for treating epilepsy). Treatment with LAMOTRIGINE NORMON should be started gradually, i.e. progressively increasing the dose for a period of 6 weeks until the maintenance dose is reached. This reduces the frequency of cutaneous reactions (see the section Take special care with LAMOTRIGINE NORMON DISPERSIBLE TABLETS)

Some formats of LAMOTRIGINE NORMON 25 mg and 50 mg DISPERSIBLE TABLETS are available as "Initiation packaging" for their use during the first weeks of the treatment when the dose has to go away increasing little by little. These "Initiation packaging" only are available for adults use. Each packaging of initiation provides the sufficient number of tablets for the first 28 days of treatment with lamotrigine. The packaging is numbered in the back part from the 1st day to the 28th day to avoid any confusion. Make sure that your doctor has given you another prescription before finishing the "Initiation packaging".

In general, the recommended treatment schedule in adults (over 12 years of age) is:

Monotherapy should start with an initial dose of 25 mg, once daily for two weeks, followed by 50 mg daily (25 mg every 12 hours) for the following two weeks. For combined therapy with valproate with or without other treatments, the initial dose should be 12.5 mg daily (one 25-mg tablet taken on alternate days) for two weeks, followed by 25 mg once daily for the following two weeks.

Both in monotherapy and combined therapy with valproate with or without other treatments, the starting package of LAMOTRIGINE NORMON 25 mg DISPERSIBLE TABLETS should be used.
- If you are using the "Initiation packaging" of LAMOTRIGINE NORMON 25 mg containing 42 dispersible tablets as monotherapy:
  • Take a tablet once a day during the first two weeks (days 1 to 14)
  • Take two tablets a day during the two following weeks (days 15 to 28). Your doctor will indicate you if you have to take two tablets once a day at the same time or a tablet two times a day.
- If you are using the "Initiation packaging" of LAMOTRIGINE NORMON 25 mg containing 21 dispersable tablets in combination with some treatment that contains valproate:
  • Take a tablet a day in alternative days during the first two weeks (days 1 to 14)
  • Take a tablet once a day during the two following weeks (days 15 to 28)

If your are taking LAMOTRIGINE NORMON DISPERSIBLE TABLETS with other antiepileptic drugs (except valproate), you should start with an initial dose of LAMOTRIGINE NORMON of 50 mg once daily for two weeks, followed by 100 mg daily (50 mg every 12 hours) for the following two weeks.

If you are taking oxcarbazepine and other drugs that modify the metabolism of lamotrigine (except valproate), you should start with an initial dose of 25 mg daily for two weeks, followed by 50 mg once daily for the following two weeks.

In children (2 to 12 years) the recommended treatment schedule in adjunctive therapy is:

Children taking valproate with or without other antiepileptic drugs should receive an initial LAMOTRIGINE NORMON dose of 0.15 mg/kg of body weight per day administered once daily for two weeks, followed by 0.3 mg/kg administered once daily for the following two weeks.

Children taking other antiepileptic drugs (except valproate) should receive an initial LAMOTRIGINE NORMON dose of 0.6 mg/kg of body weight/day administered in two doses for two weeks, followed by 1.2 mg/kg/day administered in two doses for the following two weeks.

Children taking oxcarbazepine without other drugs that modify the metabolism of lamotrigine (except valproate) should receive an initial LAMOTRIGINE NORMON dose of 0.3 mg/kg of body weight administered once daily or in two doses for two weeks, followed by 0.6 mg/kg administered once daily or in two doses for the following two weeks.

Once treatment has been started as indicated, your doctor will progressively increase the dose in accordance with the development and response to treatment until the optimum maintenance dose is reached.

BIPOLAR DISORDER:

Adults or the elderly (over 18 years of age):

The normal dose used is between 100 and 400 mg, taken once daily or divided into two doses. Treatment with LAMOTRIGINE NORMON should be started gradually, i.e. progressively increasing the dose for a period of 6 weeks until the maintenance dose is reached. This reduces the frequency of cutaneous reactions (see the section Take special care with LAMOTRIGINE NORMON DISPERSIBLE TABLETS)

• If you take more LAMOTRIGINE NORMON DISPERSIBLE TABLETS than you should:
If you have taken an excessive dose of LAMOTRIGINE NORMON DISPERSIBLE TABLETS, immediately consult your doctor or pharmacist or the Toxicology Information Service.

The symptoms of an overdose include involuntary eye movements, movement disorders, alterations to consciousness and coma (loss of consciousness) and require hospital care. Gastric lavage should be performed if considered necessary.

• If you forget to take LAMOTRIGINE NORMON DISPERSIBLE TABLETS:
If you have forgotten to take a dose, take another one as soon as you remember and then continue as before. Do not take a double dose to make up for forgotten doses.

• Effects that occur when treatment with LAMOTRIGINE NORMON DISPERSIBLE TABLETS is stopped:
Do not stop treatment with LAMOTRIGINE NORMON abruptly as it can lead to a rebound effect in the form of epileptic seizures if you are epileptic. LAMOTRIGINE NORMON should be reduced progressively over a period of 2 weeks unless your doctor indicates otherwise. Always ask your doctor first.

4. POSSIBLE SIDE EFFECTS

As with all medicines, LAMOTRIGINE NORMON DISPERSIBLE TABLETS can have adverse effects.

The most characteristic effect of lamotrigine is the development of cutaneous adverse reactions, which generally appear in the first 8 weeks after starting treatment. Most of these rashes are mild and clear up spontaneously. However, infrequently severe skin reactions may occur that are potentially life threatening. Therefore, all patients who develop a rash must be quickly evaluated and the possible withdrawal of lamotrigine should be considered.

In children, the initial appearance of rash may be confused with an infection. Therefore, parents should inform the doctor of the possibility of a reaction to lamotrigine in children who develop symptoms of rash and fever during the first eight weeks of treatment.

Frequently, adverse reactions related to the nervous system occur, such as headache, dizziness, somnolence, insomnia, tremor, vertigo and behavioural problems such as irritability or aggressiveness.

The appearance of problems with vision have also been reported.

Frequently, gastrointestinal alterations such as nausea, vomiting and diarrhoea occur.

Among the adverse effects reported very rarely are: appearance of blood anomalies (including alterations to the number of white cells and platelets), hypersensitivity syndrome, liver alterations, conjunctivitis, tics, hallucinations, agitation, instability, confusion, difficulty in maintaining balance or worsening of Parkinson's disease.

If any other adverse reaction not described in this leaflet is observed, please consult your physician or your pharmacist.

5. STORAGE OF LAMOTRIGINE NORMON DISPERSIBLE TABLETS

Keep LAMOTRIGINE NORMON DISPERSIBLE TABLETS out of the reach and sight of children.

Store below 30 °C. Protect from light and moisture.

Expiry: This drug must not be used after the expiry date shown on the packaging.

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