

# NOUMED LAMOTRIGINE

*lamotrigine chewable and dispersible tablets*

## Consumer Medicine Information

There are reports of severe, potentially life-threatening rashes associated with lamotrigine treatment, particularly in children. NOUMED LAMOTRIGINE should be discontinued at the first sign of rash unless the rash is clearly not drug-related.

### What is in this leaflet

This leaflet answers some common questions about NOUMED LAMOTRIGINE.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of taking NOUMED LAMOTRIGINE against the benefits it is expected to have for you or your child.

**If your child is being treated with NOUMED LAMOTRIGINE, follow the same instructions in this leaflet as you would as the patient.**

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What NOUMED LAMOTRIGINE is used for

NOUMED LAMOTRIGINE dispersible and chewable tablets contain the active ingredient lamotrigine.

Lamotrigine belongs to a group of medicines known as anti-epileptic medicines that are used to treat epilepsy in adults and children. NOUMED LAMOTRIGINE is used in partial or generalised seizures.

It may be used alone or in combination with other anti-epileptic medicines. In children, lamotrigine may be used only in combination with other antiepileptic medicines.

It is thought that NOUMED LAMOTRIGINE tablets work by controlling the levels of some brain chemicals that send signals to nerves.

Your doctor may have prescribed NOUMED LAMOTRIGINE for another reason.

**Ask your doctor if you have any questions about why NOUMED LAMOTRIGINE has been prescribed for you or your child.**

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

There is no evidence that lamotrigine is addictive.

### Before you take it

#### *When you must not take it*

**Do not take NOUMED LAMOTRIGINE tablets if you are allergic to lamotrigine or any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction include shortness of breath; wheezing or difficulty in breathing; swelling of the face, lips tongue or other parts of the body; rash, itching or hives on the skin.

**Do not take this medicine after the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.**

If you take it after the expiry date has passed, it may not work as well.

If it has expired or is damaged, return the pack to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

#### *Before you start to take it*

**Tell your doctor if you are taking any other medicines that contain lamotrigine.**

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you are pregnant or intend to become pregnant.**

NOUMED LAMOTRIGINE may affect your unborn baby if you take it during pregnancy but it is still important that you control your fits while you are pregnant. Your doctor will discuss the risks and benefits of taking NOUMED LAMOTRIGINE during pregnancy and help you decide whether or not you should take it.

It is recommended that women on anti-epileptic medicines, such as NOUMED LAMOTRIGINE, receive pre-pregnancy counselling with regard to the possible risk on their unborn child.

Studies have shown a decrease in the levels of folic acid during pregnancy when lamotrigine is used. It is therefore recommended that you take a folate supplement, e.g. 5 mg daily, before becoming pregnant and during the first 12 weeks of your pregnancy.

### **Tell your doctor if you are breast-feeding or planning to breast-feed.**

Lamotrigine is thought to pass into breast milk. Your doctor will discuss the risks and benefits of taking NOUMED LAMOTRIGINE tablets while breast-feeding.

### **Tell your doctor if you have or have had any medical conditions, especially the following:**

- a history of allergy or rash to other anti-epileptic drugs.
- liver or kidney problems
- Parkinson's disease, a slowly progressing "movement disorder" with symptoms such as trembling, rigid posture, slow movements and a shuffling, unbalanced walk. NOUMED LAMOTRIGINE may worsen these symptoms.
- developed meningitis after taking lamotrigine.

### **Taking other medicines**

#### **Tell your doctor if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may interfere with the absorption or action of NOUMED LAMOTRIGINE tablets.

These include:

- other medicines used to treat seizures or mental health problems including phenytoin, phenobarbitone, primidone, sodium valproate, carbamazepine, risperidone, zonisamide
- rifampicin (an antibiotic used to treat certain bacterial infections)
- lopinavir/ritonavir (used to treat HIV)
- organic cationic transporter 2 (OCT2) substrates such as dofetilide
- any form of hormonal contraceptives (e.g. oral contraceptive pills) or hormone replacement therapies (HRT)

These medicines may be affected by NOUMED LAMOTRIGINE or may affect how well it works. You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor will be able to tell you what to do when taking NOUMED LAMOTRIGINE with other medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking NOUMED LAMOTRIGINE.

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## **How to take NOUMED LAMOTRIGINE**

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### **Using it for the first time**

You may notice that you feel dizzy, tired or unsteady in the first few weeks of treatment with NOUMED LAMOTRIGINE. During this period, you may also notice that you have slight problems with your vision. As your reactions may be slower during this period, you should not operate any machinery or appliances and you should not drive a vehicle. If any of these effects do not go away or are troublesome, you should see your doctor.

### **If you develop any skin rash (e.g. spots or hives) during NOUMED LAMOTRIGINE treatment, contact your doctor immediately.**

There are reports of severe, potentially life-threatening skin rashes associated with lamotrigine treatment, particularly in children.

Treatment with lamotrigine will be discontinued unless the rash is not drug-related.

### **Tell your doctor if you have thoughts of suicide or self-harm at any time while being treated with NOUMED LAMOTRIGINE.**

### **If you have any questions about taking this medicine, ask your doctor or pharmacist.**

### **How much to take**

#### **Take NOUMED LAMOTRIGINE tablets as directed by your doctor or pharmacist. Never change the dose yourself. Do not increase the dose more quickly than you have been told.**

Your doctor and pharmacist will give you instructions on:

- how many tablets to take at each time (dose)
- how many doses to take each day
- when to take each of your doses

Your doctor may also advise you to start or stop taking other medications depending on what conditions you are being treated for and the way you respond to treatment.

If your doctor has prescribed NOUMED LAMOTRIGINE to your child for epilepsy, their weight will be checked and the dose reviewed as their weight changes.

#### **If there is something that you do not understand ask either your doctor or pharmacist.**

It is usual for the dose of NOUMED LAMOTRIGINE to start at quite a low level and be slowly increased during the first few weeks of treatment. The doses that your doctor prescribes will generally depend on your age and weight, any other medications you are taking, and your response to NOUMED LAMOTRIGINE.

Your dose may be different if:

- you have problems with your liver/kidney(s)
- you have been taking other antiepileptic medicines
- you start or stop taking hormonal contraceptive pills (oral pills)

#### **Tell your doctor if there are any changes in your menstrual pattern, such as breakthrough bleeding.**

Your doctor may need to adjust the dose of NOUMED LAMOTRIGINE as the contraceptive may not work as effectively.

**Talk to your doctor as soon as possible if you become pregnant or if you are planning to become pregnant.**

Your doctor may need to change the dose of NOUMED LAMOTRIGINE during your pregnancy.

### ***How to take it***

NOUMED LAMOTRIGINE may be taken with or without food.

The tablets may be swallowed whole, chewed or dispersed in a small volume of water (at least enough to cover the whole tablet).

### ***When to take it***

**Take your NOUMED LAMOTRIGINE tablets at about the same time each day.**

Taking your tablets at the same time each day will have the best effect. It will also help you to remember when to take the tablets.

### ***How long to take it***

**Continue taking NOUMED LAMOTRIGINE until your doctor tells you to stop.**

Most people will need to take NOUMED LAMOTRIGINE for a long time. If you stop taking NOUMED LAMOTRIGINE, your symptoms may return.

Your doctor will advise you if you need to stop taking NOUMED LAMOTRIGINE, and how to gradually reduce your dose over a period of two weeks.

### ***If you forget to take it***

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, then go back to taking it as you would normally.**

**Do not double a dose to make up for the dose you have missed.**

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.**

### ***If you take too much (overdose)***

**Immediately telephone your doctor or the Poisons Information Centre (13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has taken too many NOUMED LAMOTRIGINE tablets. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention. Keep this telephone number handy.

Symptoms of lamotrigine overdose can include:

- rapid, uncontrollable movements of the eyes
- clumsiness and lack of co-ordination affecting your balance or when walking
- dizziness, headache
- drowsiness
- blurred vision
- vomiting
- increased seizures, fits, convulsions
- loss of consciousness, coma

Taking very high doses of lamotrigine can be fatal.

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## **While you are taking it**

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Your doctor or pharmacist will give you special instructions while you or your child are being treated with NOUMED LAMOTRIGINE.

### ***Things you must do***

**Take NOUMED LAMOTRIGINE exactly as your doctor tells you to.**

Try not to miss any doses and take the medicine even if you feel well.

**Visit your doctor regularly for check-ups.**

**Tell any doctor, dentist or pharmacist who is treating you that you are taking NOUMED LAMOTRIGINE, especially if you are about to be started on any new medicine.**

**If you are to undergo a laboratory test, tell the doctor, nurse or hospital that you are taking NOUMED LAMOTRIGINE.**

Lamotrigine may interfere with some tests to detect other drugs.

**Tell your doctor immediately if you become pregnant or are trying to become pregnant while taking NOUMED LAMOTRIGINE.**

Your doctor will discuss the risks and benefits of taking this medicine during pregnancy.

**Talk to your doctor if you are breastfeeding or planning to breastfeed.**

Lamotrigine can pass into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breastfeeding while taking NOUMED LAMOTRIGINE.

**Contact your doctor immediately if you develop any skin rash (e.g. spots or hives) during treatment with NOUMED LAMOTRIGINE.**

Treatment with lamotrigine will be discontinued unless the rash is not drug-related since the effects can be severe and potentially life-threatening.

**Tell your doctor immediately if you have any suicidal thoughts or mood changes.**

Anti-epileptic medicines, including lamotrigine, may increase the risk of having suicidal thoughts and making suicide attempts. All mentions suicide or violence must be taken seriously.

**If you or someone you know have any of the following warning signs of suicide-related behaviour while being treated with NOUMED LAMOTRIGINE, contact your doctor immediately, helpline or Accident and Emergency at your nearest hospital:**

- thoughts or talk of death or suicide, or self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation

**Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.**

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

### **Things you must not do**

**Do not give this medicine to anyone else, even if they have the same condition as you.**

**Do not take NOUMED LAMOTRIGINE to treat any other complaints unless your doctor tells you to.**

**Do not take a double dose to make up for the one you have missed.**

**Do not stop taking NOUMED LAMOTRIGINE, or lower the dose, without first checking with your doctor.**

If you stop taking NOUMED LAMOTRIGINE suddenly, your epilepsy may come back or become worse. This is known as rebound seizures. Your doctor will advise you if you need to stop taking NOUMED LAMOTRIGINE tablets and how.

### **Things to be careful of**

**Be careful driving or operating machinery until you know how NOUMED LAMOTRIGINE affects you.**

NOUMED LAMOTRIGINE may make you feel drowsy, dizzy, or cause blurring of vision, which could affect your ability to drive or operate machinery. If this occurs do not drive.

If you drink alcohol, the drowsiness, dizziness or light-headedness may be worse.

**Children should not ride a bike, climb trees or do anything else that**

**could be dangerous if they are feeling, dizzy or sleepy.**

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NOUMED LAMOTRIGINE, even if the effect is not listed below.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

The most commonly reported side effects are:

- dizziness or motion problems such as tics, unsteadiness and jerkiness
- tremor
- skin rashes
- headache
- feeling sick (nausea)
- vomiting
- feeling drowsy, tired or weak
- blurred or double vision
- rapid, uncontrollable eye movements
- trouble sleeping
- irritability, aggression or agitation
- hallucinations, confusion
- increased activity in children
- joint, back or stomach pain
- respiratory or lung problems
- depression
- loss of memory
- liver problems
- diarrhoea
- dry mouth

In general, these side effects usually happen only during the first few weeks of treatment with NOUMED LAMOTRIGINE.

**If any of these side effects persist, or are troublesome, see your doctor.**

Other very rare but serious side effects may need urgent medical attention or hospitalisation.

“Lupus-like reactions” may present as a collection of symptoms consisting of fever, pain in the joints and general ill-health.

Meningitis may present as a group of symptoms consisting of fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. These may be caused by an inflammation of the membranes that cover the brain and spinal cord.

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice these serious side effects, or any of the following:**

- thoughts of suicide or self-harm
- allergic reactions
- severe skin reactions with blisters, sores or ulceration
- fainting
- high temperature, swelling of the face, enlarged lymph glands in neck, armpits or groin
- unusual bleeding or increased tendency to bleed, persistent sore throat and frequent infections and/or anaemia
- sore mouth or sore eyes
- sudden onset of severe abdominal pain associated with feeling sick (nausea) and being sick (vomiting)
- yellowing of skin and whites of eyes (jaundice) with decreased appetite and/or abdominal pain
- an increase in the frequency of seizures or convulsions
- unusual movements that you cannot control such as irregular jerking or shaking of arms and legs
- unsteadiness or loss of coordination while walking
- worsening of your symptoms if you already have Parkinson’s Disease

- temporary paralysis or weakness of muscles

Other side effects not listed above may also occur in some patients. Some of these side effects (for example, changes in your liver function) can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

**Tell your doctor if you notice anything else that is making you feel unwell, if your seizures get worse or experience new types of seizures.**

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## After taking it

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### Storage

**Keep your medicine in the blister pack until it is time to take them.**

If you take the tablets out of its original container, they may not keep well.

**Keep your medicine in a cool, dry place, protected from light, where the temperature stays below 25°C.**

Do not store it, or any other medicine, in the bathroom or near a sink. Do not leave it in the car on hot days.

Heat and dampness can destroy some medicines.

**Keep this medicine where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

If your doctor tells you to stop taking NOUMED LAMOTRIGINE or you find that they have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

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## Product description

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### What it looks like

NOUMED LAMOTRIGINE dispersible and chewable tablets are available in 4 strengths.

All tablets are white to off-white, uncoated, circular, flat and bevel-edged with a characteristic fruity odour. One side is plain while the other side is debossed to indicate the strength:

25 mg: LI2

50 mg: LI3

100 mg: LI4

200 mg: LI5

The tablets are packaged in blister packs (either Alu/PA-Alu/PVC or PVC/PvDC-Alu) of 56 tablets.

### Ingredients

#### Active ingredient

NOUMED LAMOTRIGINE tablets contain 25 mg, 50 mg, 100 mg or 200 mg of lamotrigine.

#### Inactive ingredients

- microcrystalline cellulose
- crospovidone
- calcium carbonate
- aspartame
- povidone
- hypromellose
- magnesium stearate
- maltodextrin
- purified talc
- colloidal anhydrous silica
- mixed berries flavour

NOUMED LAMOTRIGINE tablets contain aspartame, but do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

### Sponsor

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50 mg: AUST R 324706

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200 mg: AUST R 324708

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