

LAMIDUS

Lamotrigine Chewable & Dispersible Tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

Please read this leaflet carefully before you take LAMIDUS tablets.

This leaflet answers some common questions about LAMIDUS.

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. Sometimes new risks are found when a medicine has been used for many years. Your doctor has weighed the risks of you taking LAMIDUS against the benefits it is expected to have for you.

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

Keep this leaflet with this medicine. You may need to read it again.

WHAT LAMIDUS TABLET IS USED FOR

LAMIDUS tablets contain lamotrigine. Lamotrigine belongs to a group of medicines known as antiepileptic medicines.

Lamotrigine is used for the treatment of epilepsy in adults and children. It may be used alone or in combination with other antiepileptic medicines. In children, lamotrigine may be used only in combination with other antiepileptic medicines.

LAMIDUS is used in partial or generalised seizures.

It is thought that LAMIDUS tablets work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

Your doctor may have prescribed LAMIDUS tablets for another reason.

Ask your doctor if you have any questions about why LAMIDUS has been prescribed for you.

LAMIDUS tablets are not recommended for treatment in children under 2 years of age.

There is no evidence that lamotrigine is addictive.

LAMIDUS tablets may affect your ability to drive a car or operate machinery.

BEFORE YOU TAKE LAMIDUS TABLETS

When you must not take it

Do not take LAMIDUS tablets if you are allergic to LAMIDUS tablets (see Side Effects) or any of the ingredients listed at the end of this leaflet (see Ingredients).

Do not take LAMIDUS tablets after the expiry date printed on the pack.

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

Do not take LAMIDUS if the tablets do not look quite right.

Do not take LAMIDUS tablets if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you have any allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

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

LAMIDUS 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 LAMIDUS during pregnancy and help you decide whether or not you should take LAMIDUS.

It is recommended that women on antiepileptic medicines, such as LAMIDUS, receive pre-pregnancy counselling with regard to the risk on their unborn child.

Studies have shown a decrease in the levels of folic acid during pregnancy with LAMIDUS. It is therefore recommended that you take a folate supplement, e.g. 5 mg folate 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.

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

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

- you have any liver or kidney problems
- you have Parkinson's disease, a slowly progressing "movement disorder" with symptoms such as trembling, rigid posture, slow movements and a shuffling, unbalanced walk. LAMIDUS may worsen these symptoms.
- you have a history of allergy or rash to other antiepileptic drugs.

If you have not told your doctor about any of the above, tell them before you use LAMIDUS tablets.

Taking other medicines

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

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

These include:

- Rifampicin (an antibiotic used to treat certain bacterial infections)
- Phenytoin, sodium valproate, carbamazepine, phenobarbitone, primidone (used to treat epilepsy)
- Lopinavir/ritonavir (used to treat HIV)
- Risperidone (used to treat schizophrenia)
- Felbamate/zonisamide (used to treat seizures)
- Any form of hormonal contraceptives (eg. oral contraceptive pills) or hormone replacement therapies (HRT)

These medicines may be affected by LAMIDUS tablets, or may affect how well they work. You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist will be able to tell you what to do when taking/being given LAMIDUS tablets

with other medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking LAMIDUS tablets.

HOW LAMIDUS TABLETS ARE GIVEN

Using LAMIDUS tablets for the first time

You may notice that you feel dizzy, tired or unsteady in the first few weeks of treatment with LAMIDUS tablets. 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 car. If any of these effects do not go away or are troublesome, you should see your doctor.

Tell your doctor immediately if you have any suicidal thoughts or mood changes Persons taking antiepileptic medicines, including lamotrigine, may be more likely to think about killing themselves or actually doing so.

If you or someone you know demonstrate any of the following warning signs of suicide-related behaviour while taking LAMIDUS, contact a healthcare provider immediately, or even go to the nearest hospital for treatment:

- 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

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

There are reports of skin rash associated with LAMIDUS treatment. Some of these may be serious and cause severe illness.

If you have any questions about taking LAMIDUS tablets, ask your doctor or pharmacist.

How much to take

Take LAMIDUS 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 be able to tell you:

- How many tablets to take at each dose
- How many doses to take each day
- When to take each of your doses

The label on the container that the tablets were supplied in will give the same information. If there is something that you do not understand ask either your doctor or pharmacist.

It is usual for the dose of LAMIDUS tablets 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 any other antiepileptic medications you are taking for the treatment of epilepsy and your response to LAMIDUS tablets.

Your dose may be different if:

- You have problems with your liver/kidney(s)

- You have been taking other antiepileptic medicines which need to be discontinued
- You are taking hormonal contraceptive pills (oral pills)

If you start or stop taking hormonal contraceptives (e.g. the pill) while taking LAMIDUS, your doctor may need to adjust the dose of LAMIDUS depending on how well your condition is being treated.

You should tell your doctor if there are any changes in your menstrual pattern, such as breakthrough bleeding.

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

How to take it

LAMIDUS tablets may be taken with or without food. LAMIDUS tablets can either be swallowed whole with a full glass of water or chewed or dispersed in water (at least enough to cover the whole tablet).

When to take it

Take your LAMIDUS 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 LAMIDUS tablets until your doctor tells you to stop.

Most people will need to take LAMIDUS tablets for long periods. If you stop taking LAMIDUS tablets your symptoms may return. If you need to discontinue LAMIDUS tablets, your doctor would advise you to stop taking LAMIDUS tablets only after reducing your daily doses over a period of two weeks.

Use in Children

LAMIDUS is not recommended for treatment of epilepsy in children under 2 years of age.

Epilepsy: Children's weight should be checked and the dose reviewed as weight changes occur.

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 much of LAMIDUS tablets. Do this even if there are no signs of discomfort or poisoning.

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

If too many LAMIDUS tablets have been taken, it is likely that the following symptoms will be experienced:

- Rapid, uncontrollable movements of the eyes
- Unsteadiness when walking

- Dizziness, headache
- Clumsiness and lack of co-ordination
- Drowsiness
- Blurred vision
- Increased seizures/fits/convulsions
- Loss of consciousness
- Coma
- Vomiting

WHILE YOU ARE USING LAMIDUS TABLETS

Your doctor or pharmacist will be able to tell you whether there are any special instructions while you are taking LAMIDUS tablets

Things you must remember

Take LAMIDUS tablets 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 all doctors, dentists and pharmacists who are treating you that you are taking LAMIDUS tablets.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking LAMIDUS tablets.

If you become pregnant or are trying to become pregnant while taking LAMIDUS tablets, tell your doctor immediately.

There may be an increased risk of babies developing a cleft lip or cleft palate if LAMIDUS tablets are taken during the first few months of pregnancy.

Talk to your doctor if you're breast feeding or planning to breast feed.

The active ingredient of LAMIDUS passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breastfeeding while you're taking LAMIDUS.

If you develop any skin rash (e.g. spots or hives) during treatment with LAMIDUS tablets, contact your doctor immediately. There are reports of skin rash associated with LAMIDUS treatment. Some of these may be serious and cause severe illness.

Tell your doctor if you have thoughts of suicide or self-harm at any time during the treatment period.

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

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

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 use LAMIDUS tablets to treat any other complaints unless your doctor tells you to.

Do not stop taking LAMIDUS tablets, or lower the dose, without first checking with your doctor.

Epilepsy: If you stop taking LAMIDUS tablets 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 LAMIDUS tablets and how.

If you are unsure whether you should stop taking LAMIDUS tablets talk to your doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how LAMIDUS affects you.

LAMIDUS tablets may make you feel drowsy, dizzy, or cause blurring of vision, which could affect your ability to drive or operate machinery. Make sure you know how to react to LAMIDUS tablets before you drive a car, operate machinery, or do anything else that could be dangerous if you are not alert. 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.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LAMIDUS, even if the problem 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.

Most commonly reported side effects are:

- Dizziness/unsteadiness
- Headache
- Drowsiness
- Feeling sick (nausea)
- Vomiting
- Feeling weak
- Double vision
- Blurred vision
- Tremor
- Trouble sleeping
- Loss of memory
- Confusion
- Irritability/aggression
- Agitation
- Increased activity in children
- Joint/back pain

Other reported side effects include:

- Diarrhoea
- Liver problems
- Tiredness or feeling sleepy
- Seeing, feeling or hearing things that are not there (hallucination)

In general, these side effects usually happen only during the first few weeks of treatment with LAMIDUS. If any of these side effects persist, or are troublesome, see your doctor.

Ask your doctor or pharmacist any questions you may have.

Another rare side effect is "Lupus-like reactions" which may present as a collection of symptoms consisting of fever, pain in the joints and general ill-health.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- Thoughts of suicide or self-harm
- Allergic reactions- symptoms usually include:

- Shortness of breath, wheezing, or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin
- 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 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

A very rare side effect is meningitis which may present as a group of symptoms consisting of fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. This may be caused by an inflammation of the membranes that cover the brain and spinal cord.

These are very serious side effects. You may need urgent medical attention or hospitalisation. All these side effects are very rare.

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. Tell your doctor if you notice anything else that is making you feel unwell.

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

AFTER USING IT

Storage

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

If you take the tablets out of the box or the blister pack they may not keep well.

Keep your LAMIDUS in a cool, dry place where it stays below 25°C. Keep the tablets dry and protect them from light.

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.

Return any unused or expired medicine to your pharmacist

Disposal

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

PRODUCT DESCRIPTION

What it looks like

LAMIDUS 25 mg are white to off-white, uncoated, circular flat beveled tablets debossed with "LI2" on one side and plain on the other side having characteristic fruity odour. Available in packs of 56 tablets.

LAMIDUS 50 mg are white to off-white, uncoated, circular flat beveled tablets debossed with "LI3" on one side and plain on the other side having characteristic fruity odour. Available in packs of 56 tablets.

LAMIDUS 100 mg are white to off-white, uncoated, circular flat beveled tablets debossed with "LI4" on one side and plain on the other side having characteristic fruity odour. Available in packs of 56 tablets.

LAMIDUS 200 mg are white to off-white, uncoated, circular flat beveled tablets debossed with "LI5" on one side and plain on the other side having characteristic fruity odour. Available in packs of 56 tablets.

Ingredients

Active ingredient

The active ingredient in LAMIDUS tablets is lamotrigine.

LAMIDUS 25 mg tablets - 25 mg of lamotrigine

LAMIDUS 50 mg tablets - 50 mg of lamotrigine

LAMIDUS 100 mg tablets - 100 mg of lamotrigine

LAMIDUS 200 mg tablets - 200 mg of lamotrigine

Inactive ingredients

Microcrystalline cellulose, calcium carbonate, maltodextrin, crospovidone, povidone, Mixed Berries 501161 AP0551, aspartame, hypromellose, purified talc, colloidal anhydrous silica, magnesium stearate.

Australian Registration numbers

LAMIDUS 25 mg: AUST R 116720

LAMIDUS 50 mg: AUST R 116730

LAMIDUS 100 mg: AUST R 116731

LAMIDUS 200 mg: AUST R 116732

SPONSOR

LAMIDUS is supplied in Australia by:

Ranbaxy Australia Pty Ltd.

(A Sun Pharma Company)

9-13 Waterloo Road

Macquarie Park NSW 2113

Australia

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