

LOGEM®

**Lamotrigine Chewable/Dispersible Tablets,
25 mg, 50 mg and 100 mg**



What is in this leaflet

This leaflet answers some common questions about LOGEM.

It does not contain all 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 you taking LOGEM against the benefits they expect it will have for you.

If you have concerns about using this medicine ask your doctor or pharmacist.

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

What LOGEM is used for

Your LOGEM tablets contain the active ingredient, lamotrigine. Lamotrigine belongs to a group of medicines called anticonvulsants (an anti-epileptic medicine).

LOGEM tablets are used for the treatment of epilepsy in adults and children 2 years and over. LOGEM tablets are used in addition to other medicines for the treatment of epilepsy.

LOGEM is used in partial seizures (seizures that affect only one part of the brain) or generalised seizures (seizures that affect the whole brain) including tonic-clonic seizures and seizures associated with Lennox-Gastaut Syndrome.

An epileptic seizure, fit or turn results when abnormal electrical

impulses occur in nerve cells in the brain. These abnormal electrical impulses are believed to be due to altered levels of some chemicals in the brain. It is thought that LOGEM tablets work by changing the levels of some of the chemicals associated with seizures.

LOGEM can also be used to prevent mood episodes, mainly depressive episodes, in adults with bipolar disorder. Bipolar disorder is a mental illness with disturbances in thinking, feelings and behaviour.

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

Your doctor may have prescribed LOGEM for another reason.

There is no evidence that LOGEM is addictive.

LOGEM is available only with a doctor's prescription.

Before you take LOGEM

When you must not take it

Do not take LOGEM if you have an allergy to:

- **LOGEM or any medicine containing lamotrigine**
- **any of the ingredients listed at the end of this leaflet.**

Some symptoms of an allergic reaction may 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.

Do not take LOGEM tablets if you are pregnant, trying to become

pregnant or breastfeeding, unless your doctor says you should.

LOGEM 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.

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

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

Studies have shown a decrease in the levels of folic acid during pregnancy with lamotrigine. 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.

LOGEM is thought to pass into breast milk.

Your doctor will discuss the risks and benefits of using LOGEM tablets if you are pregnant or breastfeeding.

Do not take LOGEM tablets after the expiry date (EXP) printed on the pack.

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

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

Do not take LOGEM if you have previously stopped taking LOGEM or lamotrigine due to aseptic meningitis or serious skin problems such as Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN).

If you are not sure whether you should be taking LOGEM tablets, talk to your doctor.

Before you start to take it

You must tell your doctor if you:

- are allergic to foods, dyes, preservatives or any other medicines
- have previously stopped taking LOGEM or lamotrigine due to aseptic meningitis or other problems
- have a history of allergy to other antiepileptic medicines or have had a rash during treatment with any other antiepileptic medicines
- are taking any form of hormonal contraceptive (e.g. "the pill") or HRT
- have Parkinson's disease
- are suffering, or have ever suffered, from any liver or kidney disorders.
- are taking any other medication for epilepsy. This is particularly important for sodium valproate ("Epilim"). Also carbamazepine, phenobarbitone, phenytoin or primidone.
- are taking atazanavir/ritonavir or lopinavir/ritonavir, medicines used to treat HIV
- are taking dofetilide, a medicine used to treat abnormal rhythms of the heart
- are taking rifampicin, which is used to treat infections, including tuberculosis.
- you are taking any other medicines containing lamotrigine
- if you have a condition called Brugada syndrome (a genetic disease that affects the heart), or other heart problems.
- you have a serious immune system condition (haemophagocytic lymphohistiocytosis or HLH), in which the part of

the body that fights disease is overactive.

Tell your doctor if you are taking risperidone, a medicine used to treat bipolar disorder. You may be more likely to feel sleepy or drowsy when you take risperidone and lamotrigine together.

Taking other medicines

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

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking LOGEM with other medicines.

Your doctor will have a complete list of the medicines that may cause problems when taken with LOGEM.

Make sure that your doctor is aware of any of the above before you start taking LOGEM tablets.

How to take LOGEM

Using LOGEM for the first time

You may notice that you feel dizzy, tired, or unsteady in the first few weeks of treatment with LOGEM. During this period you may also notice that you have slight problems with your vision such as blurred or double 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.

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

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

If you have any questions about taking LOGEM ask your doctor or pharmacist.

How much to take

Take LOGEM 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.

It is usual for the dose of LOGEM 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, and your response to LOGEM.

Children taking LOGEM should have their weight checked and the dose of LOGEM reviewed as weight changes occur.

If you are taking hormonal contraceptives e.g. "the pill" your doctor may prescribe a higher maintenance dose, depending on how well your condition is being treated.

Your doctor will usually decrease your dose once you stop taking hormonal contraceptives.

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

If you have any questions about the dose that you have been prescribed you should ask your doctor or pharmacist.

How to take it

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

If you have any questions about how to take LOGEM ask your doctor or pharmacist.

How long to take it

Do not stop taking LOGEM tablets, or change the dose of LOGEM without first checking with your doctor.

Use in children

LOGEM 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 LOGEM

If you have forgotten to take your dose of LOGEM contact your doctor immediately.

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

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

While you are taking LOGEM

Things you must do

Contact your doctor as soon as possible if your seizures get worse or you think LOGEM is not helping your condition.

If you develop any skin rash (e.g. spots or 'hives') or other skin symptoms during LOGEM treatment contact your doctor immediately and tell them that you are taking LOGEM.

There are reports of skin rash associated with lamotrigine treatment. Some of these may be serious and cause severe illness. You may need hospital treatment or drug withdrawal.

These include potentially life-threatening skin rashes such as Stevens-Johnson syndrome (SJS)

and toxic epidermal necrolysis (TEN). **These skin rashes may appear initially as reddish target-like spots or circular patches often with central blisters on the trunk.**

Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).

These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.

The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Lamotrigine or LOGEM, you must not be re-started on Lamotrigine or LOGEM at any time.

Tell your doctor if you notice worsening of your condition, particularly depression and including development of new symptoms, if you suffer from bipolar disorder.

Tell your doctor immediately if you have any distressing thoughts (thought of suicide or self-harm) or experiences any time during treatment with LOGEM.

Tell all doctors, dentists and pharmacists who are treating you that you are taking LOGEM.

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

If you are going to have any laboratory tests, tell your doctor or hospital that you are taking LOGEM. It may interfere with the results of some tests.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not stop taking LOGEM just because you feel better.

If you stop taking LOGEM 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 LOGEM and how.

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

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

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use LOGEM to treat any other complaints unless your doctor says you should.

Things to be careful of

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

As with other anticonvulsant medicines for the treatment of epilepsy, LOGEM may cause dizziness and drowsiness in some people, and affect alertness. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous. If you drink alcohol, 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.

If you take too much (overdose)

Immediately contact your doctor or Poisons Information Centre 0800 POISON or 0800 764 766 for advice or go to Accident or Emergency department at your nearest hospital, if you think that you or anyone else may have taken too many LOGEM tablets. Do this even if there are no signs

of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

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

If too many LOGEM tablets have been taken, the following symptoms may be more likely to experience the following side effects which may be fatal: nausea, vomiting, tiredness/drowsiness, problems with eyesight, rapid or uncontrollable eye movements, twitching, impaired consciousness, clumsiness or lack of coordination, unsteadiness, convulsions, changes in your heart beat and coma.

Side effects

Check with your doctor as soon as possible if you have any problems or feel unwell while taking LOGEM, even if you are not sure the problems are connected with the medicine.

Like other medicines, LOGEM can cause some side effects. If they occur, they are often minor and temporary. However, some may be serious and need medical attention. Ask your doctor to answer any questions you may have.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

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

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported rarely. If you develop a rash or skin symptoms, seek immediate advice from a doctor and tell them that you are taking LOGEM.

Tell your doctor if you notice any of the following and they worry you:

- dizziness/unsteadiness
- headache
- drowsiness
- feeling sick (nausea), vomiting
- diarrhoea
- feeling weak
- movement problems such as tics, unsteadiness, jerkiness and tremor (shakiness)
- double vision, blurred vision
- trouble sleeping
- confusion
- loss of memory
- irritability/aggression
- agitation
- increased activity in children
- joint or back pain
- diarrhoea
- liver problems
- tiredness or feeling sleepy
- hallucinations
- nightmares
- unusual hair loss or thinning (alopecia)
- a decrease in antibodies (immunoglobulins).
- any skin reaction (e.g. skin rash, 'hives', spots, or blisters)
- swelling of the face, lips or tongue
- sore mouth or sore eyes
- a high temperature (fever)
- swollen glands
- drowsiness
- enlarged liver and/or spleen with pain and/or tenderness in the region towards the top of the stomach
- easy bruising or unusual bleeding
- yellow of the eyes or skin (jaundice)
- a mood disorder other than the one being treated (e.g. mania)
- severe depression, thoughts of suicide, aggressive behaviour, recurrence of a previous mental illness, or seeing or hearing things that are not there
- suicide attempts

Some people may have changes in their blood count, which may make them feel tired, short of breath and more susceptible to infections. They may also bleed or bruise very easily or have mouth ulcers or a sore throat.

These are the more common side effects of LOGEM.

Anti-epileptic medicines are used to treat several conditions, including epilepsy and bipolar disorder. Information from a large number of studies in patients being treated with anti-epileptic medicines such as lamotrigine has shown a small number of reports of suicidal behaviour (including suicidal thoughts and suicide attempts).

Tell your Doctor immediately or go to the Accident and Emergency department of your nearest hospital if you have any thoughts of harming yourself or committing suicide.

Tell your doctor immediately if you notice any of the following:

If you are taking LOGEM for epilepsy, rarely, you may start to experience more seizures than usual. Tell your doctor as soon as possible if your seizures get worse or if you have a new type of seizure. These are all very serious side effects and you may need urgent medical attention or hospitalisation.

Serious side effects are rare.

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.

The above list includes very serious side effects and you may need urgent medical attention or hospitalisation.

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

A serious immune system condition, in which the part of the body system that fights disease is overactive, has been reported while taking

lamotrigine. Although, it has been reported very rarely, it can be life-threatening, so it is important that you know the symptoms to look out for. Symptoms include:

- a high temperature (fever).
- skin rashes
- trouble walking or seeing, and fits (seizures) for the first time or happening more often
- enlarged liver and/or spleen with pain and/or tenderness in the region towards the top of the stomach
- yellowing of the skin and/or eyes
- swollen glands in the neck, armpit and/or groin
- bleeding and/or bruising more easily; looking pale, feeling tired.

In most cases these symptoms may be signs of less serious side effects, but you must be aware that they can be signs of a condition which can be serious if not recognised early.

If you think you are having an allergic reaction to LOGEM tablets, TELL YOUR DOCTOR IMMEDIATELY or go to the Accident or Emergency department at your nearest hospital. Symptoms usually include some or all of the following:

- wheezing
- swelling of the face, lips, tongue or other parts of the body
- difficulty in breathing
- sudden or severe itching, skin rash, or hives
- fainting

If you are a female, tell your doctor if your menstrual periods change.

After taking LOGEM

Storage

Keep LOGEM tablets where young children cannot reach them.

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

Keep your tablets in the container that they were supplied in.

The container has been designed to help protect the tablets. If you take the tablets out of the pack they may not keep well.

Keep LOGEM tablets in a cool dry place where the temperature stays below 25°C.

Do not store LOGEM tablets, or any other medicine, in a bathroom or near a sink.

Do not leave LOGEM tablets in the car or on window sills.

Heat and dampness may affect the tablets.

Disposal

If your doctor tells you to stop taking LOGEM, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What LOGEM tablets look like

LOGEM 25 mg chewable/dispersible tablets are white to off-white, round, tablets. They are marked with "LY" over "25" on one side and plain on the other.

LOGEM 50 mg chewable/dispersible tablets are white to off-white, round, tablets. They are marked with "LY" over "50" on one side and plain on the other.

LOGEM 100 mg chewable/dispersible tablets are white to off-white, round, tablets. They are marked with "LY" over "100" on one side and plain on the other.

Ingredients

Active ingredient:

LOGEM contains 25 mg, 50 mg or 100 mg of lamotrigine as the active ingredient.

Inactive ingredients:

LOGEM also contains:

- mannitol,
- microcrystalline cellulose,
- povidone,
- silicon dioxide,
- sodium starch glycollate,
- magnesium stearate,
- saccharin sodium
- artificial blackcurrant flavouring.

LOGEM tablets contain saccharin and sulfites.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

LOGEM is supplied in New Zealand by:

Viatrix Ltd
PO Box 11-183
Eilerslie
AUCKLAND
www.viatrix.co.nz
Telephone 0800 168 169

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Logem® is a Viatrix company trade mark.