LOGEM®

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about taking LOGEM, speak to your doctor or pharmacist.

WARNING: There are reports of severe, potentially life-threatening rashes associated with Lamotrigine treatment, particularly in children. LOGEM should be discontinued at the first sign of rash unless the rash is clearly not medicine related.

1. Why am I taking LOGEM?

LOGEM contains the active ingredient lamotrigine. LOGEM is used to treat epilepsy.

For more information, see Section <u>1. Why am I taking</u> LOGEM? in the full CMI.

2. What should I know before I take LOGEM?

Do not take if you have ever had an allergic reaction to LOGEM or any of the ingredients listed at the end of the CML

Talk to your doctor if you have any other medical conditions, take any other medicines, pregnant or breastfeeding or plan to become pregnant or breastfeed.

For more information, see Section 2. What should I know before I take LOGEM? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LOGEM and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take LOGEM?

 LOGEM may be swallowed whole, chewed or dispersed in a small volume of water (at least enough to cover the whole tablet). More instructions can be found in Section <u>4. How do I take LOGEM?</u> in the full CMI.

5. What should I know while taking LOGEM?

Things you should do

 Remind any doctor, dentist or pharmacist you visit that you are taking LOGEM.

	 Contact your doctor immediately if you develop any skin rash such as spots or 'hives' during LOGEM treatment.
Things you should not do	 For epilepsy patients, do not stop taking LOGEM or change the dose without first checking with your doctor. Do not take a double dose to make up for any that you may have missed.
Driving or using machines	 Make sure you know how you react to LOGEM before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy.
Looking after your medicine	 Store LOGEM tablets below 25°C. Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of

the pack, it will not keep well.

For more information, see Section <u>5. What should I know while using LOGEM?</u> in the full CMI.

6. Are there any side effects?

Common side effects include dizziness, movement problems, tremors, skin rash, headache, nausea, vomiting, feeling drowsy or tired, blurred or double vision, rapid, uncontrollable eye movements, trouble sleeping, feeling sleepy, 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, diarrhea, dry mouth. Serious side effects include serious skin and allergic reactions, liver and blood problems.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> effects? in the full CMI

WARNING: There are reports of severe, potentially life-threatening rashes associated with Lamotrigine treatment, particularly in children. LOGEM should be discontinued at the first sign of rash unless the rash is clearly not medicine related.

LOGEM®

Active ingredient(s): Lamotrigine

Consumer Medicine Information (CMI)

This leaflet provides important information about taking LOGEM. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking LOGEM.

Where to find information in this leaflet:

- 1. Why am I taking LOGEM?
- 2. What should I know before I take LOGEM?
- 3. What if I am taking other medicines?
- 4. How do I take LOGEM?
- 5. What should I know while taking LOGEM?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking LOGEM?

LOGEM contains lamotrigine as the active ingredient and belongs to a group of medicines called "antiepileptic medicine".

Anti-epileptic medicine such as LOGEM, are used to treat epilepsy in patients over 2 years of age. Epilepsy is a condition where you have repeated seizures (fits).

In general, it is initially used in addition to other medicines, for the treatment of epilepsy including partial or generalised seizures and Lennox- Gastaut syndrome.

It is thought that LOGEM works by changing the levels of some chemicals associated with seizures.

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

Your doctor may have prescribed it for another reason.

There is no evidence that LOGEM is addictive.

2. What should I know before I take LOGEM?

Warnings

Do not take LOGEM if:

- you are allergic to any medicine containing lamotrigine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can take LOGEM.

Symptoms of an allergic reaction may include:

- shortness of breath;
- wheezing or difficulty in breathing;
- swelling of the face, lips, tongue or any other parts of the body;
- rash, itching or hives on the skin.

Do not take LOGEM after the expiry date printed on the pack has passed.

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

If it has expired or is damage, return it to your pharmacist for disposal.

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

Check with your doctor if you have or have had any of the following medical conditions:

- a history of allergy or rash to other anti-epileptic medicine
- liver or kidney disease
- Parkinson's disease
- if you have ever developed meningitis after taking lamotrigine

Tell your doctor if you are:

- taking any other medicines that contain lamotrigine
- allergic to any other medicines or any foods, dyes or preservatives
- take any medicines for any other condition

 During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor immediately if you become pregnant or if you are planning to become pregnant.

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

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

It is recommended that women on anti-epileptic medicine, such as LOGEM, receive pre-pregnancy counselling regarding the possible risk to their unborn child.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

LOGEM can pass into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking LOGEM if you are breastfeeding.

Use in children

LOGEM is not recommended in children under 2 years of age. Children's weight should be checked and the dose reviewed as weight changes with growth occur.

3. What if I am taking other medicines?

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

Some medicines may interfere with LOGEM and affect how it works. These include:

- valproate and carbamazepine, used to treat both epilepsy and mental health problems
- any form of hormonal medicine, e.g. "the pill" or HRT
- other anti-epileptic medicine, e.g. phenytoin, primidone or phenobarbital
- OCT2 substrates such as dofetilide
- rifampicin, an antibiotic, which is used to treat infections, including tuberculosis
- medicines used to treat Human Immunodeficiency Virus (HIV) infection
- risperidone, used to treat mental health problems.

These medicines may be affected by LOGEM or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LOGEM.

4. How do I take LOGEM?

Taking 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. As your reactions may be slower during this period you should not operate any machinery or drive a car. If any of these effects do not go away or are troublesome you should see your doctor.

Ask your doctor or pharmacist if you have any questions about taking LOGEM.

How much to take

It may take a while to find the best dose of LOGEM for you. The dose you take will depend on:

- your age and weight
- whether you are taking LOGEM with other medications
- whether you have any kidney or liver problems

Never take more LOGEM than your doctor tells you to.

Do not increase the dose more quickly than you have been told.

Your doctor will prescribe a low dose to start and gradually increase the dose over a few weeks until you reach a dose that works for you.

Women taking hormonal contraceptives, such as the birth control 'pill' may need a higher maintenance dose of LOGEM. Your doctor will usually decrease your dose once you stop taking hormonal contraceptives.

Tell your doctor if there are any changes in your menstrual pattern such as breakthrough bleeding whilst on the 'pill'.

Your doctor may need to adjust the dose of LOGEM as the 'pill' may not work as effectively for contraception whilst taking it.

When to take LOGEM

Talk to your doctor or pharmacist to work out when it is best for you to take your doses of LOGEM.

How to take LOGEM

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

It can be taken with or without food.

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

How long to take it

Continue taking your medicine for as long as your doctor tells you.

LOGEM helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

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

Your doctor will advise you if you need to stop taking LOGEM and how to do this gradually over a period of two weeks.

If you forget to take LOGEM

LOGEM should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember and then go back to taking it as you would normally.

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

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

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

If you take too much LOGEM

If you take too much LOGEM, you may be more likely to have serious side effects which may be fatal.

Symptoms of overdose can include rapid, uncontrollable eye movements, clumsiness and lack of coordination affecting your balance, impaired or loss of consciousness, fits or coma.

If you think that you or anyone else has taken too much LOGEM, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking LOGEM?

Things you should do

- Take LOGEM exactly as your doctor has prescribed.
- Contact your doctor immediately if you develop any skin rash, like spots or hives, during LOGEM treatment.

There are reports of severe, potentially life-threatening rashes associated with LOGEM treatment particularly in children. LOGEM should be discontinued at the first

sign of rash unless the rash is clearly not medicine related.

 Contact your doctor if you experience a rash or sunburn after taking LOGEM and having been exposed to sun or artificial light, e.g. solarium.

Your doctor will check your treatment and may advise you to avoid sunlight or protect yourself against the sun, e.g. use of a sunscreen and/or to wear protective clothing.

- Tell any other doctors, dentists and pharmacists who are treating you that you are taking LOGEM, especially if you are about to start on any new medicines.
- If you require a blood test or laboratory test, tell your doctor or hospital that you are taking LOGEM.

LOGEM may interfere with some laboratory tests to detect other drugs.

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

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

 Talk to your doctor if you are breastfeeding or intend to breastfeed.

LOGEM can pass into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking LOGEM if you are breastfeeding.

- Keep all of your doctor's appointments so that your progress can be checked.
- Seek immediate medical attention if you experience symptoms such as fever, rash or enlarged/swollen lymph nodes whilst taking LOGEM.
- Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

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

Remind any doctor, dentist or pharmacist you visit that you are taking LOGEM.

Things you should not do

 Do not stop taking LOGEM, even if you feel better, or change the dose without first checking with your doctor.

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 to do it gradually over about 2 weeks.

- Do not take a double dose to make up for the dose you may have missed.
- Do not give LOGEM to anyone else even if their symptoms seem similar to yours.
- Do not take LOGEM to treat any other complaints unless your doctor tells you to.

Things to be careful of

 Tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital if you or someone you know has any suicidal thoughts or other mental/mood changes.

All mentions of suicide or violence must be taken seriously. Families and caregivers of children and adolescents who are taking LOGEM should be especially watchful for any changing behaviour.

Anti-epileptic medicines such as LOGEM may increase the risk of suicidal behaviour (including suicidal thoughts and suicide attempts).

 Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling dizzy or sleepy.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Make sure you know how you react to LOGEM before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store your tablets below 25°C.
- Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the pack, it will not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If your doctor tells you to stop taking LOGEM or your tablets have passed their expiry date, take it to your pharmacist for safe disposal.

Do not use LOGEM after the expiry date.

6. Are there any side effects?

Tell your doctor as soon as possible if you do not feel well while you are taking LOGEM

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Less serious side effects

Less serious side effects	What to do
 dizziness movement problems such as tics, unsteadiness and jerkiness tremors skin rash headache nausea vomiting 	Speak to your doctor if you have any of these less serious side effects.

Less serious side effects	What to do
 feeling drowsy or tired 	
 blurred or double vision 	
 rapid, uncontrollable eye movements 	
trouble sleeping	
feeling sleepy	
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 during the first few weeks of treatment with LOGEM.

Serious side effects

Serious side effects	What to do
 liver and blood problems drowsiness itching abdominal pain or tenderness feeling very tired easy bruising or unusual bleeding a sore throat, or more infections such as a cold, than usual yellow skin (jaundice). uncontrollable repeated body movements and/or sounds or words (tics). 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
Serious Allergic skin reactions:	
 any skin reaction, e.g. rash or 'hives' or red nodules or patches on the skin skin rash or sunburn after exposure to sun or artificial light (photosensitivity) 	

Serious side effects	What to do
 wheezing, difficulty in breathing 	
 swelling of the face, lips or tongue 	
sore mouth or sore eyes	
• fever	
• swollen glands	

Your doctor may decide to carry out tests on your liver, kidneys or blood and may tell you to stop taking LOGEM if you experience these rare symptoms.

Tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital if you or someone you know has any suicidal thoughts or other mental/mood changes whilst taking LOGEM.

All mentions of suicide or violence must be taken seriously. Families and caregivers of children and adolescents who are taking LOGEM should be especially watchful for any changing behaviour.

Anti-epileptic medicines such as LOGEM may increase the risk of suicidal behaviour (including suicidal thoughts and suicide attempts).

Potentially serious skin reaction

A small number of people taking LOGEM get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems if they are not

treated. Severe allergic reactions are rare. This risk may be associated with a variant in genes in people from Asian origin (mainly Han Chinese and Thai). If you are of such origin and have been tested previously carrying this genetic variant (HLA-B* 1502), discuss this with your doctor before taking LOGEM.

These symptoms are more likely to happen during the first few months of treatment with LOGEM, especially if the dose is too high or if the dose is increased too quickly, or if LOGEM is taken with a medicine called valproate. Serious skin reactions are more common in children.

Potentially serious aseptic meningitis

LOGEM increases the risk of developing aseptic meningitis, which is a serious inflammation of the protective membrane that covers the brain and spinal cord.

Many of the side effects already listed are symptoms of this condition, as well as light sensitivity, stiff neck, muscle pains and chills.

Potentially serious / life threatening arrhythmia

If you have had a fast heartbeat, heart failure, or other heart problems, you should not take lamotrigine. LOGEM may cause you to have an abnormal heartbeat, which could lead to sudden death. Symptoms include a fast, slow, or pounding heartbeat, shortness of breath, chest pain, and feeling lightheaded.

Tell your doctor if you notice any of these symptoms.

If you are taking LOGEM for epilepsy, tell your doctor as soon as possible if your seizures get worse or if you have a new type of seizure.

You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell, even if you think the problems are not connected with LOGEM and are not referred to in this leaflet.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

LOGEM is only available with a doctor's prescription.

What LOGEM contains

Active ingredient (main ingredient)	lamotrigine
Other ingredients (inactive ingredients)	cellulose - microcrystalline sodium starch glycollate povidone purified water silicon dioxide saccharin sodium artificial blackcurrant flavour mannitol magnesium stearate.
Potential allergens	saccharin sulfites

LOGEM dispersible/chewable tablets come in 4 different strengths: 25 mg, 50mg, 100 mg & 200 mg.

Do not take LOGEM if you are allergic to any of these ingredients.

What LOGEM looks like

LOGEM 25 - white to off-white, round, flat faced, bevelled edge tablets with "LY" over "25" on one side and plain on the other side (AUST R 99059).

LOGEM 50 - white to off-white, round, flat faced, bevelled edge tablets with "LY" over "50" on one side and plain on the other side (AUST R 99360).

LOGEM 100 - white to off-white, round, flat faced, bevelled edge tablets with "LY" over "100" on one side and plain on the other side (AUST R 99062).

LOGEM 200 - white to off-white, round, flat faced, bevelled edge tablets with "LY" over "200" on one side and plain on the other side (AUST R 99064).

LOGEM tablets are available in blister packs of 56 tablets.

Who distributes LOGEM

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

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www.viatris.com.au

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This leaflet was prepared in October 2025.

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