

Arrow - Lamotrigine

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Arrow - Lamotrigine?

Arrow - Lamotrigine contains the active ingredient lamotrigine. Arrow - Lamotrigine tablets are used to treat epilepsy in adults and children aged 2 years and over. It is also used to prevent mood episodes in adults 18 years of age and over with bipolar disorder, predominantly by preventing depressive episodes.

For more information, see Section [1. Why am I using Arrow - Lamotrigine?](#) in the full CMI.

2. What should I know before I use Arrow - Lamotrigine?

Do not use if you have ever had an allergic reaction to Arrow - Lamotrigine or any of the ingredients listed at the end of the CMI.

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

For more information, see Section [2. What should I know before I use Arrow - Lamotrigine?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Arrow - Lamotrigine 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 use Arrow - Lamotrigine?

- It is usual for the dose of Arrow - Lamotrigine 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 anti-epileptic medications you are taking and your response to Arrow - Lamotrigine tablets.

More instructions can be found in Section [4. How do I use Arrow - Lamotrigine?](#) in the full CMI.

5. What should I know while using Arrow - Lamotrigine?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or nurse you visit that you are using Arrow - Lamotrigine.• Tell your doctor immediately if you become pregnant or intend to become pregnant whilst using Arrow - Lamotrigine.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly without checking with your doctor.• Do not use Arrow - Lamotrigine tablets to treat any other complaints unless your doctor says to.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Arrow - Lamotrigine affects you
Drinking alcohol	<ul style="list-style-type: none">• If you are drinking alcohol while using the medicine dizziness or light headedness may be worse.• Children should not ride a bike or climb trees or do anything else that could be dangerous if they are feeling dizzy or sleepy.
Looking after your medicine	<ul style="list-style-type: none">• Store it in a cool dry place below 25°C. Protect from light.

For more information, see Section [5. What should I know while using Arrow - Lamotrigine?](#) in the full CMI.

6. Are there any side effects?

Side effects that have been reported to be less serious include headache, dizziness, vomiting, pain in back and joints, skin rash, tiredness and liver problems. Tell your doctor immediately if you have any thoughts of harming yourself or committing suicide.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Arrow - Lamotrigine

Active ingredient: *Lamotrigine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Arrow - Lamotrigine. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Arrow - Lamotrigine.**

Where to find information in this leaflet:

- [1. Why am I using Arrow - Lamotrigine?](#)
- [2. What should I know before I use Arrow - Lamotrigine?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Arrow - Lamotrigine?](#)
- [5. What should I know while using Arrow - Lamotrigine?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Arrow - Lamotrigine?

Arrow - Lamotrigine contains the active ingredient Lamotrigine.

Arrow - Lamotrigine tablets are used for the treatment of epilepsy in adults and children aged 2 years and older.

Lamotrigine (the active ingredient in Arrow - Lamotrigine tablets) belongs to a group of medicines called "anti-epileptic drugs".

Epilepsy: Usually Arrow - Lamotrigine tablets are initially used in addition to other medicines for the treatment of epilepsy.

Arrow - Lamotrigine is used in partial or generalised seizures including Lennox-Gastaut Syndrome.

It is thought that Arrow - Lamotrigine tablets work by changing the levels of some chemicals associated with seizures.

Arrow - Lamotrigine is also used to prevent mood episodes in adults 18 years of age and over with bipolar disorder, predominantly by preventing depressive episodes.

Your doctor may have prescribed Arrow - Lamotrigine tablets for another reason.

Arrow - Lamotrigine tablets are not addictive.

2. What should I know before I use Arrow - Lamotrigine?

Warnings

Do not use Arrow - Lamotrigine if:

- you have ever had an allergic reaction to Arrow - Lamotrigine tablets (See "6. Are there any side effects?") or any of the ingredients listed toward the end of this leaflet. (See "Product details").
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- are allergic to foods, dyes, preservatives or any other medicines.
- have a history of allergy or rash to other antiepileptic drugs.
- are suffering, or have ever suffered, from any liver or kidney disorders.
- have Parkinson's disease.
- have ever developed meningitis after taking lamotrigine.
- have a condition called Brugada syndrome (a genetic disease that affects the heart), or other heart problems.
- have a serious immune system condition (haemophagocytic lymphohistiocytosis or HLH), in which the part of the body that fights disease is overactive

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Arrow - 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 Arrow - Lamotrigine during pregnancy and help you decide whether or not you should take Arrow - Lamotrigine.

Check with your doctor if you are pregnant or intend to become pregnant.

It is recommended that women on antiepileptic drugs, such as Arrow - Lamotrigine, 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 lamotrigine therapy. 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.

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

Arrow - Lamotrigine is thought to pass into breast milk.

Your doctor will discuss the risks and benefits of using Arrow - Lamotrigine tablets if you are breastfeeding.

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 which are similar to Arrow - Lamotrigine should not be used together as an overdose may result.

Some medicines may affect how Arrow - Lamotrigine works, or make it more likely that you'll have side effects. These include:

- sodium valproate ("Epilim" or "Valpro").
- oestrogen-containing products, including hormonal contraceptive (e.g. "the pill", ethinylestradiol/levonorgestrel) or hormone replacement therapy (HRT).
- any other anti-epileptic drugs (e.g. carbamazepine, phenobarbitone, phenytoin or primidone).
- any medicines you buy without a prescription
- rifampicin, which is used to treat infections, including tuberculosis.
- medicine which is used to treat Human Immunodeficiency Virus (HIV) infection (e.g. lopinavir/ritonavir or atazanavir/ritonavir).
- dofetilide, a medicine used to treat heart problems.
- 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.
- any other medicines containing lamotrigine.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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

4. How do I use Arrow - Lamotrigine?

How much to take

Take Arrow - 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 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 Arrow - Lamotrigine 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 anti-epileptic medications you are taking for the treatment of epilepsy and your response to Arrow - Lamotrigine tablets.

Most people need a higher maintenance dose of Arrow - Lamotrigine tablets when they take hormonal contraceptives, so if you are taking these, your doctor may increase your dose. 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.

Your doctor may need to change the dose of Arrow - Lamotrigine during your pregnancy.

Children

Arrow - Lamotrigine 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.

How to take Arrow - Lamotrigine

Arrow - Lamotrigine tablets may be swallowed whole, chewed or dispersed in a small volume of water (at least enough to cover the whole tablet). Never take only part of the liquid.

If you forget to use Arrow - Lamotrigine

Arrow - Lamotrigine should be used regularly at the same time each day as instructed by your doctor. This will help to keep you free of symptoms throughout the day and night.

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 your medicine, ask your pharmacist for some hints.

If you use too much Arrow - Lamotrigine

If you think that you have used too much Arrow - Lamotrigine, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 0800 764 766), 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.

If too many Arrow - Lamotrigine tablets have been taken, you may be more likely to experience the following serious

side effects which may be fatal: nausea, vomiting, tiredness/drowsiness and problems with eyesight, rapid or uncontrollable eye movements, twitching, impaired consciousness, clumsiness or lack of coordination, unsteadiness, convulsions, changes in your heartbeat and coma.

5. What should I know while using Arrow - Lamotrigine?

Things you should do

Your doctor or pharmacist will be able to tell you whether there are any special instructions while you are taking Arrow - Lamotrigine tablets.

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

There are reports of serious skin rash with Arrow - Lamotrigine that may need hospital treatment or drug withdrawal; rarely serious skin rash may cause death.

Tell your doctor or pharmacist that you are taking Arrow - Lamotrigine tablets if you are about to be started on any new medicines.

Arrow - Lamotrigine may interfere with some laboratory tests to detect other drugs. If you require a laboratory test, tell your doctor or hospital that you are taking Arrow - Lamotrigine.

Call your doctor straight away if you:

- are planning to become pregnant. There may be an increased risk of babies developing a cleft lip or cleft palate if Arrow - Lamotrigine tablets are taken during the first few months of pregnancy.
- are breast feeding or planning to breast feed.
- the active ingredient of Arrow - Lamotrigine passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breastfeeding while you're taking Arrow - Lamotrigine.
- for any reason, you have not taken your medicine exactly as directed.

Remind any doctor, dentist, pharmacist or nurse you visit that you are using Arrow - Lamotrigine.

Things you should not do

- stop taking Arrow - Lamotrigine tablets just because you feel better
- stop using this medicine suddenly or lower the dosage without checking with your doctor.
- take Arrow - Lamotrigine to treat any other complaints unless your doctor tells you to.
- give your medicine to anyone else, even if they have the same condition as you.

Epilepsy: If you stop taking Arrow - Lamotrigine 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 Arrow - Lamotrigine tablets and how.

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Arrow - Lamotrigine affects you.

As with other anticonvulsant medicines for the treatment of epilepsy, Arrow - Lamotrigine may cause dizziness and drowsiness in some people and affect alertness.

Make sure you know how you react to Arrow - Lamotrigine 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.

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.

Looking after your medicine

Keep Arrow - Lamotrigine tablets in the container that they were supplied in until time to take them.

Keep Arrow - Lamotrigine tablets in a cool dry place where the temperature stays below 25°C. Protect from light.

Do not leave in a car, on a window sill or in the bathroom.

Keep it 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.

When to discard your medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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.

You may notice that you feel dizzy, tired, or unsteady in the first few weeks of treatment with Arrow - Lamotrigine 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.

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

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

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

Less serious side effects

Less serious side effects	What to do
<p>Nervous system disorders:</p> <ul style="list-style-type: none"> dizziness/unsteadiness movement problems such as tics, unsteadiness and jerkiness drowsiness trouble sleeping tremor (shakiness) increased activity in children <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> diarrhea feeling sick, also called nausea vomiting <p>Psychiatric disorders:</p> <ul style="list-style-type: none"> hallucinations nightmares loss of memory confusion irritability/aggression agitation <p>Skin and subcutaneous disorders:</p> <ul style="list-style-type: none"> rash unusual hair loss or thinning (alopecia) <p>Eye disorders:</p> <ul style="list-style-type: none"> double vision, blurred vision <p>General disorders:</p> <ul style="list-style-type: none"> tiredness or feeling sleepy joint or back pain feeling weak runny nose headache <p>Immune system disorders:</p> <ul style="list-style-type: none"> a decrease in antibodies (immunoglobulins) changes in blood count which may make them feel tired, short of breath and more susceptible to infections 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> bleed or bruise very easily or have mouth ulcers or a sore throat. <p>Hepatobiliary disorders:</p> <ul style="list-style-type: none"> liver problems trouble sleeping 	
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In general, these side effects usually happen only during the first few weeks of treatment with Arrow - Lamotrigine. If any of these side effects persist, or are troublesome, see your doctor.

Serious side effects

Serious side effects	What to do
<p>Psychotic disorders</p> <ul style="list-style-type: none"> Suicidal thoughts Suicide attempts <p>Allergic reactions</p> <ul style="list-style-type: none"> Wheezing Swelling of the face, lips or tongue Hayfever Fainting Sore mouth or sore eyes. Swollen glands <p>Skin and subcutaneous disorders:</p> <ul style="list-style-type: none"> rash or hives red nodules or patches on the skin (pseudolymphoma) erythema multiforme easy bruising or unusual bleeding Yellow skin (jaundice) <p>Musculoskeletal and connective tissue disorders:</p> <ul style="list-style-type: none"> "Lupus like reactions" which may present as a collection of symptoms consisting of fever, pain in the joints and general ill- health <p>Nervous system disorders:</p> <ul style="list-style-type: none"> Increase in seizure frequency 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 	<p>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.</p> <p>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.</p> <p>Tell your doctor as soon as possible if your seizures get worse or if you have a new type of seizure</p>

Serious side effects	What to do
<p>Immune system disorders A serious immune system condition, in which the part of the body system that fights disease is overactive, has been reported while taking Arrow - 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:</p> <ul style="list-style-type: none"> • 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. 	<p>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.</p> <p>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.</p>

Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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 via <https://pophealth.my.site.com/carmreportnz/s/>.

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

7. Product details

This medicine is only available with a doctor's prescription.

What Arrow - Lamotrigine contains

Active ingredient (main ingredient)	Lamotrigine (2, 5, 25, 50,100 or 200 mg). The amount depends on which strength of Arrow - Lamotrigine you have been given.
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Other ingredients (inactive ingredients)	Mannitol, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, povidone, saccharin sodium, purified talc, magnesium stearate and blackcurrant flavour.
Potential allergens	none

Arrow - Lamotrigine tablets do not contain gluten.

Arrow - Lamotrigine tablets do not contain lactose.

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

What Arrow - Lamotrigine looks like

Arrow - Lamotrigine dispersible/chewable tablets come in 6 different strengths.

ARROW – LAMOTRIGINE chewable/dispersible tablet 2 mg	TT50-7587
Arrow - Lamotrigine chewable/dispersible tablet 5 mg	TT50-7587a
Arrow - Lamotrigine chewable/dispersible tablet 25 mg	TT50-7587b
Arrow - Lamotrigine chewable/dispersible tablet 50 mg	TT50-7587c
Arrow - Lamotrigine chewable/dispersible tablet 100 mg	TT50-7587d
Arrow - Lamotrigine chewable/dispersible tablet 200 mg	TT50-7587e

Arrow - Lamotrigine 2 mg: White to off-white, round tablets embossed with 'LI' over '2' on one side and 'D' on the other side. Pack sizes of 30 and 56 tablets.

Arrow - Lamotrigine 5 mg: White to off-white, oval tablet, embossed with 'LI' scoreline '5' on one side and 'D' on the other side. Pack sizes of 30 and 56 tablets.

Arrow - Lamotrigine 25 mg: White to off-white, shield-shaped tablet, embossed with 'D' over 'LI25' on one side and a scoreline on the other side. Pack sizes of 56 tablets

Arrow - Lamotrigine 50 mg: White to off-white, shield-shaped tablet, embossed with 'D' over 'LI50' on one side and a scoreline on the other side. Pack sizes of 56 tablets

Arrow – Lamotrigine 100 mg: White to off-white, shield-shaped tablet, embossed with 'D' over 'LI100' on one side and a scoreline on the other side. Pack sizes of 56 tablets

Arrow - Lamotrigine 200 mg: White to off-white, shield-shaped tablet, embossed with 'D' over 'LI200' on one side and a scoreline on the other side. Pack sizes of 56 tablets.

Not all strengths or pack sizes may be marketed in New Zealand.

Who distributes Arrow - Lamotrigine

Teva Pharma (New Zealand) Limited
PO Box 128 244
Remuera
Auckland 1541
Telephone: 0800 800 097

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