

## **ARROW - LAMOTRIGINE**

Lamotrigine 2 mg, 5 mg, 25 mg, 50 mg, 100 mg and 200 mg dispersible/chewable tablets

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### **What is in this leaflet**

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This leaflet answers some common questions about ARROW - 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 benefits and risks. Your doctor has weighed the risks of you taking ARROW - LAMOTRIGINE against the benefits he/she expects it will have for you.

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

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

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### **What ARROW - LAMOTRIGINE is used for**

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Lamotrigine, the active ingredient in ARROW - LAMOTRIGINE tablets, belongs to a group of medicines called "anti-epileptic drugs".

ARROW - LAMOTRIGINE is used to treat epilepsy in adults and children. It is usually used in addition to other medicines for the treatment of epilepsy. ARROW - LAMOTRIGINE is used in partial or generalised seizures including Lennox-Gastaut Syndrome.

Epileptic seizures, fits or turns result 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. ARROW - LAMOTRIGINE is thought to work by changing the levels of some of the 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 for another reason. Ask your doctor if you have any questions about why ARROW - LAMOTRIGINE has been prescribed for you.

There is no evidence that ARROW - LAMOTRIGINE tablets are addictive.

ARROW - LAMOTRIGINE is available only with a doctor's prescription.

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## **Before you take ARROW - LAMOTRIGINE**

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

**Do not take ARROW - LAMOTRIGINE if you are allergic to medicines containing lamotrigine, or any of the ingredients listed at the end of this leaflet.**

Some of the 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
- lumpy skin rash ("hives"), hayfever or fainting.

**Do not take ARROW - LAMOTRIGINE if you are pregnant or intend to become pregnant, unless your doctor says you should.**

Studies have shown a decrease in the levels of folic acid during pregnancy with lamotrigine therapy. Thus, lamotrigine may affect your unborn baby if you take it during pregnancy. However, it is still important that you control your fits while you are pregnant. Your doctor will discuss the risks and benefits of taking lamotrigine if you are pregnant. It is recommended that women on anti-epileptic drugs receive pre-pregnancy counselling with regard to the risk on their unborn child.

**Do not take ARROW - LAMOTRIGINE if you are breastfeeding or intend to breastfeed, unless your doctor says you should.**

Lamotrigine passes into breast milk. Your doctor will discuss the risks and benefits of taking lamotrigine if you are breastfeeding.

**Do not take ARROW - LAMOTRIGINE if the expiry date (Exp.) printed on the pack has passed.**

It may not work well if you do.

**Do not take ARROW - LAMOTRIGINE if the packaging is torn or shows signs of tampering.**

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

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

**Tell your doctor if you have any medical conditions, especially liver or kidney disorders.**

**Tell your doctor if you are taking other medications for epilepsy. This is particularly important for tablets containing sodium valproate (Epilim™).**

**Tell your doctor if you ever had a rash during treatment with any other anti-epileptic drugs.**

### ***Taking other medicines***

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

Some medicines may be affected by ARROW - LAMOTRIGINE, or may affect how well it works. These include:

- other anti-epileptic drugs, eg sodium valproate, carbamazepine or phenobarbitone
- any form of hormonal contraceptive, eg "the pills" or hormone therapy.

Your doctor can tell you what to do if you are taking these medicines. If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ARROW - LAMOTRIGINE.

**If you have not told your doctor about any of the above, tell him/her before you start taking ARROW - LAMOTRIGINE.**

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## **How to take ARROW - LAMOTRIGINE**

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**Follow all directions given to you by your doctor and pharmacist carefully. Never change the dose yourself. Do not increase the dose more quickly than you have been told.**

### ***How much to take ARROW - LAMOTRIGINE***

It is usual for the dose of ARROW - 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 any other anti-epileptic medications you are taking, and your response to ARROW - LAMOTRIGINE.

Your doctor and pharmacist will 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.

If you start or stop taking hormonal contraceptives (eg "the pill") while taking ARROW - LAMOTRIGINE, your doctor may need to adjust the lamotrigine dose depending on how well your condition is being treated.

### ***Use in children***

Children's weight should be checked and the dose be 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).

***How long to take ARROW - LAMOTRIGINE***

The length of your treatment will depend on the condition you are being treated with and on how well you respond to the treatment. Do not stop taking ARROW - LAMOTRIGINE or change the dose without first checking with your doctor.

If you have any questions about taking ARROW - LAMOTRIGINE, ask your doctor or pharmacist.

***If you forget to take ARROW - LAMOTRIGINE***

**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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.**

**Do not take a double dose to make up for the dose you 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 ARROW - LAMOTRIGINE (overdose)***

**Immediately telephone your doctor, or the National Poisons Information Centre (0800 POISON or 0800 764 766), or go to the Accident and Emergency department at your nearest hospital, if you think that you or anyone else may have taken too many ARROW - LAMOTRIGINE tablets.**

**Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

**Keep the telephone numbers for these places handy.**

Some of the symptoms of an overdose may include nausea, vomiting, tiredness, drowsiness and problems with eyesight, twitching, impaired consciousness and/or coma.

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**While you are taking ARROW - LAMOTRIGINE**

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

***Things you must do***

**If you develop any skin rash, such as spots or "hives", during ARROW - LAMOTRIGINE therapy, 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.

**Tell your doctor immediately or go to the nearest hospital for treatment if you have any suicidal thoughts or behaviour, depression or other mood changes, especially if these symptoms are severe, abrupt in onset or not part of your normal symptoms during ARROW - LAMOTRIGINE therapy.**

There are reports of an increase risk of suicidality in patients who are treated with anti-epileptic drugs for epilepsy, psychiatric disorders or other conditions. The following are the warning signs of suicide-related behaviour:

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

All mentions of suicide or violence must be taken seriously.

**Before starting any new medicine, tell your doctor or pharmacist that you are taking ARROW - LAMOTRIGINE.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking ARROW - LAMOTRIGINE.**

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

**For females, tell your doctor if your menstrual periods change during ARROW - LAMOTRIGINE therapy.**

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

Otherwise, your doctor may think that it is not working and change your treatment unnecessarily.

***Things you must not do***

**Do not stop taking ARROW - LAMOTRIGINE just because you feel better.**

Stopping ARROW - LAMOTRIGINE suddenly may cause your epilepsy to come back or become worse. This is known as "rebound seizures".

Your doctor will advise you if you need to stop taking ARROW - LAMOTRIGINE and how. If you are not sure how you should stop taking ARROW - LAMOTRIGINE, talk to your doctor or pharmacist.

**Do not change the dose of your ARROW - LAMOTRIGINE without checking with your doctor.**

**Do not use ARROW - LAMOTRIGINE to treat any other conditions unless your doctor tells you to.**

**Do not give ARROW - LAMOTRIGINE to anyone else, even if their symptoms seem similar to yours.**

***Things to be careful of***

**Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking ARROW - LAMOTRIGINE until you know how it affects you.**

As with other anti-epileptic drugs, 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.

If you drink alcohol, dizziness and 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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***Taking ARROW - LAMOTRIGINE for the first time***

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

**Severe, potentially life-threatening rashes have been reported in association with the use of lamotrigine, particularly in children. Thus, stop taking ARROW - LAMOTRIGINE at the first sign of rash unless the rash is clearly not drug related.**

**If you develop any skin rash such as spots or "hives" during ARROW - LAMOTRIGINE treatment, contact your doctor immediately.**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ARROW - LAMOTRIGINE.**

Like other medicines, ARROW - LAMOTRIGINE can cause some 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.

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

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

**The most commonly reported side effects are:**

- dizziness, unsteadiness
- rash
- headache
- drowsiness
- nausea (feeling sick), vomiting
- diarrhoea
- feeling weak
- tremor (shakiness)
- blurred or double vision
- sleeping problems
- confusion
- irritability (aggression/agitation is less common)
- increased activity in children
- joint or back pain.

In general, these side effects usually only occur during the first few weeks of treatments with ARROW - LAMOTRIGINE. If any of these side effects persist or are troublesome, see your doctor.

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

- any skin reaction such as rash or "hives"
- suicidal thoughts or behaviour
- swelling of the face, lips or tongue
- sore mouth or sore eyes
- high temperature or fever
- swollen glands
- unusual bleeding or bruising more easily than normal.

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

**Other rare to very rare side effects are:**

- liver problems
- movement problems such as tics, unsteadiness, jerkiness
- hallucinations
- Lupus-like reactions, which may present as a collection of symptoms consisting of fever, pain in the joints and general ill-health.

**If you think you are having an allergic reaction to ARROW - LAMOTRIGINE tablets, tell your doctor immediately or go to Accident and Emergency at the nearest hospital. Symptoms of an allergic reaction may include some of all of the following:**

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- lumpy skin rash ("hives"), hayfever or fainting.

This is not a complete list of all possible side effects. Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

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## **After taking ARROW - LAMOTRIGINE**

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### ***Storage***

**Keep ARROW - LAMOTRIGINE where children cannot reach it.**

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

**Keep ARROW - LAMOTRIGINE in a cool, dry place where the temperature stays below 25°C. Protect tablets from light and moisture.**

**Keep your tablets in the packs until it is time to take them.**

If you take the tablets out of the pack, they may not keep well.

**Do not store ARROW - LAMOTRIGINE or other medicines in the bathroom or near a sink.**

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

Heat, light and dampness can destroy some medicines.

### ***Disposal***

If your doctor tells you to stop taking ARROW - LAMOTRIGINE, or your tablets 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 ARROW - LAMOTRIGINE looks like***

ARROW - LAMOTRIGINE is available in 6 different strengths of tablets:

- 2 mg - white to off-white, round tablet embossed with 'L1' over '2' on one side and 'S' on the other side
- 5 mg - white to off-white, oval tablet, embossed with 'L1|5' on one side and 'S' on the other side
- 25 mg - white to off-white, shield-shaped tablet, embossed with 'S' over 'L125' on one side and a scoreline on the other side
- 50 mg - white to off-white, shield-shaped tablet, embossed with 'S' over 'L150' on one side and a scoreline on the other side
- 100 mg - white to off-white, shield-shaped tablet, embossed with 'S' over 'L1100' on one side and a scoreline on the other side

- 200 mg - white to off-white, shield-shaped tablet, embossed with 'S' over 'LI200' on one side and a scoreline on the other side.

All strengths of ARROW - LAMOTRIGINE tablets are available in blister packs of 56 tablets. In addition, the 2 mg and 5 mg tablets are also available in blister packs of 30 tablets.

### ***Ingredients***

The active ingredient in ARROW - LAMOTRIGINE tablets is lamotrigine:

- each ARROW - LAMOTRIGINE 2 tablet contains 2 mg of lamotrigine
- each ARROW - LAMOTRIGINE 5 tablet contains 5 mg of lamotrigine
- each ARROW - LAMOTRIGINE 25 tablet contains 25 mg of lamotrigine
- each ARROW - LAMOTRIGINE 50 tablet contains 50 mg of lamotrigine
- each ARROW - LAMOTRIGINE 100 tablet contains 100 mg of lamotrigine
- each ARROW - LAMOTRIGINE 200 tablet contains 200 mg of lamotrigine.

The tablets also contain:

- mannitol
- microcrystalline cellulose
- croscarmellose sodium
- colloidal anhydrous silica
- povidone
- saccharin sodium
- purified talc
- magnesium stearate
- blackcurrant flavour.

*The tablets do not contain gluten, sucrose, tartrazine or any azo dyes.*

### ***Supplier***

ARROW - LAMOTRIGINE is distributed in New Zealand by:

#### **Arrow Pharmaceuticals (NZ) Limited**

Mount Eden Central Business Park  
33a Normanby Road, Mt Eden  
Auckland, New Zealand.

### ***Date of preparation***

27 August 2010