

Approved Patient Information Leaflet for Medicines for Human Use:

RIGADEL

SCHEDULING STATUS: S3

RIGADEL 25 mg Tablets

RIGADEL 50 mg Tablets

RIGADEL 100 mg Tablets

RIGADEL 200 mg Tablets

Lamotrigine

Contain sugar: lactose monohydrate

RIGADEL 25 mg contains 29,950 mg lactose monohydrate.

RIGADEL 50 mg contains 59,900 mg lactose monohydrate.

RIGADEL 100 mg contains 119,800 mg lactose monohydrate.

RIGADEL 200 mg contains 239,600 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking RIGADEL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- RIGADEL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What RIGADEL is and what it is used for
2. What you need to know before you take RIGADEL
3. How to take RIGADEL
4. Possible side effects
5. How to store RIGADEL
6. Contents of the pack and other information

1. What RIGADEL is and what it is used for

The active ingredient in RIGADEL is lamotrigine.

RIGADEL belongs to a group of medicines called anti-epileptics. It is used to treat two conditions – epilepsy and bipolar disorder.

RIGADEL treats epilepsy by blocking the signals in the brain that trigger epileptic seizures (fits)

- For adults and children aged 12 years and over, RIGADEL is indicated as monotherapy (using a single medicine or therapy) or add-on (with other medicines) treatment of partial epilepsy, with or without secondary generalised tonic-clonic seizures and in primary generalised tonic-clonic seizures.
- For children aged between 2 and 12 years, RIGADEL can be used with other medicines, to treat those conditions (partial epilepsy with or without secondary generalised tonic-clonic seizures) that were not fully controlled with other antiepileptic medicines.
- RIGADEL can also be used with other medicines to treat the seizures that occur with a condition called Lennox-Gastaut syndrome.

RIGADEL also treats bipolar disorder

People with bipolar disorder (sometimes called manic depression) have extreme mood swings, with periods of mania (excitement or euphoria) alternating with periods of

depression (deep sadness or despair). For adults aged 18 years and over, RIGADEL can be used on its own or with other medicines, to prevent the periods of depression that occur in bipolar disorder.

2. What you need to know before you take RIGADEL

Do not take RIGADEL

- if you are hypersensitive (allergic) to lamotrigine or any of the other ingredients of RIGADEL (listed in section 6).

Warnings and precautions

Take special care with RIGADEL

Talk to your doctor or pharmacist before taking RIGADEL:

- if you have any kidney problems
- if you have ever developed a rash after taking lamotrigine or other medicines for bipolar disorder or epilepsy
- if you experience a rash or sunburn after taking lamotrigine 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)
- if you have ever developed meningitis after taking lamotrigine (read the description of these symptoms in Section 4 of this leaflet: Rare side effects)
- if you are already taking medicine that contains lamotrigine
- if you have a condition called Brugada syndrome. Brugada syndrome is a genetic disease that results in abnormal electrical activity within the heart. ECG abnormalities which may lead to dysrhythmias (abnormal heart rhythm) can be triggered by lamotrigine.

If any of these applies to you:

Tell your doctor, who may decide to lower the dose or that RIGADEL is not suitable for you.

Important information about potentially life-threatening reactions

A small number of people taking RIGADEL get an allergic reaction or potentially life-threatening skin reaction, which may develop into more serious problems if they are not treated. These can include Stevens–Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). You need to know the symptoms to look out for while you are taking RIGADEL.

Haemophagocytic lymphohistiocytosis (HLH)

There have been reports of a rare but very serious immune system reaction, in patients taking lamotrigine.

Contact your doctor or pharmacist immediately if you experience any of the following symptoms while taking lamotrigine: fever, rash, neurological symptoms (e.g. shaking or tremor, confusional state, disturbances of brain function).

Thoughts of harming yourself or suicide

Anti-epileptic medicines are used to treat several conditions, including epilepsy and bipolar disorder. People with bipolar disorder can sometimes have thoughts of harming themselves or committing suicide. If you have bipolar disorder, you may be more likely to think like this:

- when you first start treatment
- if you have previously had thoughts about harming yourself or about suicide
- if you are under 25 years old.

If you have distressing thoughts or experiences, or if you notice that you feel worse or develop new symptoms while you're taking RIGADEL:

See a doctor as soon as possible or go to the nearest hospital for help.

You may find it helpful to tell a family member, caregiver or close friend that you can become depressed or have significant changes in mood and ask them to read this leaflet. You might ask them to tell you if they are worried about your depression or other changes in your behaviour.

A small number of people being treated with anti-epileptics such as RIGADEL have also had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

If you're taking RIGADEL for epilepsy

The seizures in some types of epilepsy may occasionally become worse or happen more often while you're taking RIGADEL. Some patients may experience severe seizures, which may cause serious health problems. If your seizures happen more often or if you experience a severe seizure while you're taking RIGADEL:

See a doctor as soon as possible.

RIGADEL should not be given to people aged under 18 years to treat bipolar disorder. Medicines to treat depression and other mental health problems increase the risk of suicidal thoughts and behaviour in children and adolescents aged under 18 years.

Other medicines and RIGADEL

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Your doctor needs to know if you are taking other medicines to treat epilepsy or mental health problems.

This is to make sure you take the correct dose of RIGADEL. These medicines include:

- oxcarbazepine, felbamate, gabapentin, levetiracetam, pregabalin, topiramate or zonisamide, used to treat epilepsy
- lithium, olanzapine or aripiprazole used to treat mental health problems
- bupropion, used to treat mental health problems or to stop smoking
- paracetamol, used to treat pain and fever

Tell your doctor if you are taking any of these.

Some medicines interact with RIGADEL or make it more likely that people will have side effects. These include:

- valproate, used to treat epilepsy and mental health problems
- carbamazepine, used to treat epilepsy and mental health problems
- phenytoin, primidone, mesuximide or phenobarbitone, used to treat epilepsy
- risperidone, used to treat mental health problems
- rifampicin, which is an antibiotic
- medicines used to treat Human Immunodeficiency Virus (HIV) infection (a combination of lopinavir and ritonavir or atazanavir and ritonavir)
- hormonal contraceptives, such as the Pill (see below).

Tell your doctor if you are taking any of these or if you start or stop taking any.

Hormonal contraceptives (such as the Pill) can affect the way RIGADEL works

Your doctor may recommend that you use a particular type of hormonal contraceptive or another method of contraception, such as condoms, a cap or coil. If you are using a hormonal contraceptive like the Pill, your doctor may take samples of your blood to check the level of RIGADEL. If you are using a hormonal contraceptive or if you plan to start using one:

Talk to your doctor, who will discuss suitable methods of contraception with you.

RIGADEL can also affect the way hormonal contraceptives work, although it's unlikely to make them less effective. If you are using a hormonal contraceptive and you notice any changes in your menstrual pattern, such as breakthrough bleeding or spotting between periods:

Tell your doctor. These may be signs that RIGADEL is affecting the way your contraceptive is working.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking RIGADEL.

Driving and using machines

RIGADEL can cause dizziness and double vision.

Don't drive or use machines unless you are sure you're not affected.

If you have epilepsy, talk to your doctor about driving and using machines.

It is not always possible to predict to what extent RIGADEL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which RIGADEL affects them.

RIGADEL contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking RIGADEL.

3. How to take RIGADEL

Do not share medicines prescribed for you with any other person.

Always take RIGADEL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

- your age
- whether you are taking RIGADEL with other medicines
- whether you have problems with your kidneys or liver.

Your doctor will start you on a low dose, and gradually increase the dose over a few weeks until you reach a dose that works for you. Never take more RIGADEL than your doctor tells you to.

The usual effective dose of RIGADEL for adults and children aged over 12 years is between 100 mg and 400 mg each day.

RIGADEL is not recommended for children aged under 2 years.

RIGADEL should be taken at the same time every day, with or without food. Try to take it the same way, since taking RIGADEL with food may change the time it takes to be absorbed.

If you have the impression that the effect of RIGADEL is too strong or too weak, tell your doctor or pharmacist.

Method of administration

- Take the tablets with a sufficient quantity of liquid (e.g. one glass of water)
- RIGADEL should be taken at the same time every day, with or without food.

If you take more RIGADEL than you should

If you take too much RIGADEL you may be more likely to have serious side effects which may be fatal. Someone who has taken too much RIGADEL may have any of these symptoms:

- rapid, uncontrollable eye movements (nystagmus)

- clumsiness and lack of co-ordination, affecting their balance (ataxia)
- heart rhythm changes (detected usually on ECG)
- loss of consciousness, fits (convulsions) or coma.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. If possible, show them the RIGADEL packet.

If you forget to take RIGADEL

Do not take a double dose to make up for forgotten individual doses.

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take RIGADEL at the next regularly scheduled time.

If you stop taking RIGADEL

Contact your doctor, if you stop taking RIGADEL for any reason.

A sudden withdrawal may make your epilepsy come back, make your seizures worse, or change your behaviour. Should your doctor advise you to stop, your dose will be gradually reduced.

Do not restart RIGADEL without consulting your doctor.

4. Possible side effects

RIGADEL can have side effects.

Not all side effects reported for RIGADEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RIGADEL, please consult your health care provider for advice.

If any of the following happens, stop taking RIGADEL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- skin rashes or redness, which may develop into life-threatening skin reactions including widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*), extensive peeling of the skin (more than 30 % of the body surface – *toxic epidermal necrolysis*) or extended rashes with liver, blood and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS hypersensitivity syndrome)

These are very serious side effects. If you have them, you may have had a serious reaction to RIGADEL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Serious with less frequent side effects:

- a group of symptoms together including: fever, 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 (*meningitis*). These symptoms usually disappear once treatment is stopped however if the symptoms continue or get worse contact your doctor
- a serious disorder of blood clotting, which can cause unexpected bleeding or bruising (disseminated intravascular coagulation)
- haemophagocytic lymphohistiocytosis (HLH)
- changes which may show up in blood tests - including reduced numbers of red blood cells (*anaemia*), reduced numbers of white blood cells (*leucopenia*, *neutropenia*, *agranulocytosis*), reduced numbers of platelets (*thrombocytopenia*), reduced numbers of all these types of cell (*pancytopenia*) and a disorder of the bone marrow called *aplastic anaemia*

- uncontrollable body movements (*tics*), uncontrollable muscle spasms affecting the eyes, head and torso (*choreoathetosis*) or other unusual body movements such as jerking, shaking or stiffness
- in people who already have epilepsy, seizures happening more often
- in people who already have Parkinson's disease, worsening of the symptoms
- ulcers in the mouth, throat, nose or genitals
- a sore mouth or red or swollen eyes (*conjunctivitis*)
- a high temperature (*fever*), flu-like symptoms or drowsiness
- swelling around your face or swollen glands in your neck, armpit or groin
- unexpected bleeding or bruising, or the fingers turning blue
- a sore throat or more infections (such as colds) than usual
- increased levels of liver enzymes seen in blood tests
- an increase in a type of white blood cell (*eosinophils*)
- enlarged lymph nodes
- involvement of the organs of the body including liver and kidneys.

Serious side effects with frequency unknown:

- inflammation of the kidney (*tubulointerstitial nephritis*), or inflammation of both the kidney and the eye (*tubulointerstitial nephritis and uveitis syndrome*)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- skin rash
- irritability
- feeling sleepy or drowsy
- feeling dizzy

- shaking or tremors
- difficulty in sleeping (insomnia)
- diarrhoea
- dry mouth
- feeling sick (nausea) or being sick (vomiting)
- feeling tired
- pain in your back or joints, or elsewhere.
- clumsiness and lack of co-ordination (*ataxia*)
- double vision or blurred vision
- rapid, uncontrollable eye movements (*nystagmus*)

Less frequent side effects:

- unusual hair loss or thinning (*alopecia*)
- skin rash or sunburn after exposure to sun or artificial light (*photosensitivity*)
- itchy eyes, with discharge and crusty eyelids (*conjunctivitis*).
- a high temperature (*fever*)
- swelling around the face (*oedema*) or swollen glands in the neck, armpit or groin (*lymphadenopathy*)
- changes in liver function, which will show up in blood tests, or liver failure
- hallucinations ('seeing' or 'hearing' things that aren't really there)
- confusion
- feeling 'wobbly' or unsteady when you move about
- lupus-like reaction (symptoms may include: back or joint pain which sometimes may be accompanied by fever and/or general ill health)
- aggression
- feeling agitated

Side effects with frequency unknown:

- There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term anti-epileptic medication, have a history of osteoporosis or take steroids.
- Nightmares
- Lower immunity because of lower levels of antibodies called immunoglobulins in the blood which help protect against infection.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of RIGADEL.

5. How to store RIGADEL

Store all medicines out of reach of children

Store in a cool dry place at or below 25 °C. Protect from light.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What RIGADEL contains

- The active substance is lamotrigine.
- The other ingredients are lactose monohydrate, ferric oxide yellow, microcrystalline cellulose, polyvinyl pyrrolidone, purified water, sodium starch glycollate, purified talc, magnesium stearate.

What RIGADEL looks like and contents of the pack

RIGADEL 25 mg Tablets are pale yellow coloured, circular, flat faced bevelled edged uncoated tablets with 'L 25' embossing on one side and plain on the other side.

RIGADEL 50 mg Tablets are pale yellow coloured, circular, flat faced bevelled edged, uncoated tablets with 'L50' embossing on one side and breakline dividing 'B' & 'L' logo on the other side.

RIGADEL 100 mg Tablets are pale yellow coloured, circular, flat faced bevelled edged, uncoated tablets with 'L100' embossing on one side and breakline dividing 'B' & 'L' logo on the other side.

RIGADEL 200 mg Tablets are pale yellow coloured, circular, flat faced bevelled edged, uncoated tablets with 'L200' embossing on one side and breakline dividing 'B' & 'L' logo on the other side.

RIGADEL tablets are packed in:

Blister pack (PVC film and Aluminium foil) of 1 x 14, 2 x 14, 4 x 14, 6 x 14, 3 x 10, and 6 x 10 tablets.

Bulk pack (White HDPE Jars) of 100, 250, 500 and 1000.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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