

Consumer Medicine Information

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

What is in this leaflet

Please read this leaflet carefully before you take REEDOS tablets.

This leaflet answers some common questions about REEDOS tablets. 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 risks and benefits. Your doctor has weighed the risks of you taking REEDOS tablets against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What REEDOS is used for

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

Anti-epileptic drugs such as REEDOS tablets are used for the treatment of epilepsy in adults and children aged 2 years and older.

In general, it is initially used in addition to other medicines, for the treatment of epilepsy including partial or generalized seizures and Lennox-Gastaut Syndrome. It is thought that REEDOS tablets work by changing the levels of some chemicals associated with seizures.

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

Your doctor may have prescribed REEDOS tablets for another reason.

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

REEDOS tablets are not addictive.

Before you take REEDOS

When you must not take it

Do not take REEDOS if you have ever had an allergic reaction to REEDOS tablets (See "Side-Effects") or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")

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 this medicine after the expiry date printed on the pack has passed.

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

Before you start to take it

Tell your doctor if you are taking any other medicines that contain lamotrigine.

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

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

- a history of allergy or rash to other antiepileptic drugs.
- liver or kidney disease
- Parkinson's disease

- if you have ever developed meningitis after taking lamotrigine

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

REEDOS 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 REEDOS during pregnancy and help you decide whether or not you should take REEDOS.

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

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

Tell your doctor if you are breast feeding or planning to breast feed.

REEDOS is thought to pass into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of using REEDOS tablets if you are breastfeeding.

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

Do not take REEDOS to treat any other complaints unless your doctor says so.

Use in children

Epilepsy: REEDOS 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.

Taking other medicines

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

Some medicines may interfere with REEDOS. 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 drugs, e.g. phenytoin, primidone or phenobarbitone.
- OCT2 substrates such as defetilide.
- rifampicin, an antibiotic, which is used to treat infections, including tuberculosis.
- medicine which is used to treat Human Immunodeficiency Virus (HIV) infection.
- risperidone, used to treat mental health problems.

These medicines may be affected by REEDOS 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.

Your doctor or pharmacist has more information on medicines to avoid while taking REEDOS.

How to take REEDOS

Using REEDOS Tablets for the first time

You may notice that you feel dizzy, tired, or unsteady in the first few weeks of treatment with REEDOS 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 (eg. spots or 'hives') during REEDOS treatment contact your doctor immediately.

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

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

How much to take

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

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

Never take more REEDOS 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.

Hormonal contraceptives (such as the birth control pill) and REEDOS tablets: Women taking hormonal contraceptives, such as birth control 'pill' may need a higher maintenance dose of REEDOS tablets. 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 whilst on the 'pill'.

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

How to take REEDOS

REEDOS tablets 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

For epilepsy patients, do not stop taking REEDOS tablets, or change the dose without first checking with your doctor.

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

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident or Emergency department at your nearest hospital, if you think you or anyone else may have taken too

many REEDOS tablets, even if there are no signs of discomfort or poisoning.

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

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

While you are taking REEDOS

Things you must do

Take REEDOS exactly as your doctor has prescribed.

If you develop any skin rash (eg. spots or 'hives') during REEDOS treatment contact your doctor immediately.

There are reports of serious, potentially life-threatening rashes associated with REEDOS treatment, particularly in children. REEDOS should be discontinued at the first sign of rash unless the rash is clearly not drug related.

Tell any other doctor, dentist or pharmacist who is treating you that you are taking REEDOS tablets if you are about to be started on any new medicines. If you require a laboratory test, tell your doctor or hospital that you are taking REEDOS.

REEDOS 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 REEDOS during pregnancy.

Talk to your doctor if you're breast feeding or planning to breast feed.

REEDOS can pass into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breastfeeding while you're taking REEDOS.

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

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

Things you must not do

For epilepsy patients, do not stop taking REEDOS tablets or change the dose without first checking with your doctor.

Epilepsy: If you stop taking REEDOS 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 REEDOS tablets and how to do this gradually over about 2 weeks.

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

Things to be careful of

Be careful driving or operating machinery until you know how REEDOS tablets affect you.

Make sure you know how you react to REEDOS 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.

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

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 REEDOS should be especially watchful for any changing behaviour. Anti-epileptic medicines such as REEDOS may increase the risk of suicidal behaviour (including suicidal thoughts and suicide attempts).

Side Effects

Tell your doctor as soon as possible if you do not feel well while you are taking REEDOS tablets.

Like other medicines, REEDOS tablets can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

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

The most commonly reported side effects of REEDOS are:

- dizziness
- movement problems such as tics, unsteadiness and jerkiness
- tremors
- Skin rash
- headache
- nausea
- vomiting
- feeling drowsy or tired
- double vision or blurred 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 only during the first few weeks of treatment with REEDOS.

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 REEDOS tablets.

All mentions of suicide or violence must be taken seriously. Families and caregivers of children and adolescents who are taking REEDOS should be especially watchful for any changing behaviour. Anti-epileptic medicines such as REEDOS may increase the risk of suicidal behaviour (including suicidal thoughts and suicide attempts).

Potentially serious skin reaction

A small number of people taking REEDOS 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.

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

- Any skin reaction (e.g. rash or 'hives').

- wheezing, difficulty in breathing
- Swelling of the face, lips or tongue.
- Sore mouth or sore eyes.
- fever
- Swollen glands.

Tell your doctor immediately if you notice any of the above symptoms.

Liver and blood problems

Tell your doctor if you notice any of these symptoms:

- 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).

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

If you are taking REEDOS 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 if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet. Other side effects not listed above may also occur in some people.

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

You may not experience any of them.

After taking REEDOS

Storage

Keep REEDOS tablets in a cool dry place where the temperature stays below 25 °C and protect from moisture.

Keep REEDOS tablets 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.

Product description

What REEDOS looks like

REEDOS dispersible/chewable tablets come in 5 different strengths.

REEDOS 5

REEDOS 5 dispersible/chewable tablets are white to off-white capsule shaped uncoated tablets debossed with 'H' on one side and '81' on other side.

REEDOS 25

REEDOS 25 dispersible/chewable tablets are white to off-white, rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '80' on flat side.

REEDOS 50

REEDOS 50 dispersible/chewable tablets are white to off-white rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '79' on flat side.

REEDOS 100

REEDOS 100 dispersible/chewable tablets are white to off-white rounded square shaped

uncoated tablets debossed with 'H' on multifaceted side and '78' on flat side.

REEDOS 200

REEDOS 200 dispersible/chewable tablets 200 mg are white to off-white rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '77' on flat side.

All strengths of tablets are presented in pack size of 56 tablets in blisters, and 30 tablets & 56 tablets in bottle.

Ingredients

Active Ingredient:

Lamotrigine

Each tablet contains either 5 mg, 25 mg, 50 mg, 100 mg, 200 mg of lamotrigine.

Inactive Ingredients:

- Microcrystalline cellulose
- Magnesium carbonate hydrate
- Polacrillin potassium
- Sucralose
- Povidone
- Magnesium Stearate
- Blackcurrant 501017 AP0551 (PI106513)

Sponsor

Name and Address of the Sponsor

Fair-Med Healthcare Australia Pty. Ltd.
5/148 Spit Road, Mosman,
NSW, 2088, Australia

Australian Registration Numbers:

5 mg: (Blister pack AUST R 187263 & Bottle AUST R 187257)

25 mg: (Blister pack AUST R 187266 & Bottle AUST R 187269)

50 mg: (Blister pack AUST R 187267 & Bottle AUST R 187283)

100 mg: (Blister pack AUST R 187279 & Bottle AUST R 187258)

200 mg: (Blister pack AUST R 187280 & Bottle AUST R 187259)

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