

**DR. REDDY'S LABORATORIES (PTY) LTD.
REDILEV 250/500/750
(FILM-COATED TABLETS)
APPROVED PATIENT INFORMATION LEAFLET**

PATIENT INFORMATION LEAFLET
SCHEDULING STATUS: S3
REDILEV 250
REDILEV 500
REDILEV 750
Levetiracetam
Film-coated tablet
Sugar free
Read all of this leaflet carefully before you start taking REDILEV. - Keep this leaflet. You may need to read it again. - If you have further questions, please ask your doctor or your pharmacist. - REDILEV 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 REDILEV is and what it is used for 2. What you need to know before you take REDILEV 3. How to take REDILEV 4. Possible side effects 5. How to store REDILEV 6. Contents of the pack and other information
1. WHAT REDILEV IS AND WHAT IT IS USED FOR

DR. REDDY'S LABORATORIES (PTY) LTD.
REDILEV 250/500/750
(FILM-COATED TABLETS)
APPROVED PATIENT INFORMATION LEAFLET

REDILEV is an antiepileptic medicine (a medicine used to treat seizures in epilepsy).

REDILEV is used alone or with other antiepileptic medicines in adults and adolescents from 12 years of age for various forms of epilepsy.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE REDILEV

Do not take REDILEV:

- if you are allergic (hypersensitive) to levetiracetam or any of the other ingredients of REDILEV (See **WHAT REDILEV CONTAINS**).
- if you are pregnant or breastfeeding (See **Pregnancy and breastfeeding** below).

Warnings and precautions

Take special care with REDILEV:

- If you are over 65 years of age.
- If you have kidney or liver problems.
- If you have a family or medical history of irregular heart rhythm (visible on an electrocardiogram), or if you have a disease and/or take a treatment that make(s) you prone to heartbeat irregularities or salt imbalances.
- If you experience abnormal thoughts, feeling irritable or reacting more aggressively than usually, or if you or your family and friends notice important changes in mood or behaviour.
- Aggravation of epilepsy: Your seizures may rarely become worse or happen more often, mainly during the first month after the start of the treatment or increase of the dose. In a very rare form of early-onset epilepsy (epilepsy associated with SCN8A mutations) that causes multiple types of seizures and loss of skills you may notice that the seizures remain present or are becoming worse during your treatment.
- REDILEV can cause sleepiness and tiredness.
- REDILEV can affect the levels of blood cells seen in laboratory tests.
- REDILEV can affect seizure control during pregnancy.

**DR. REDDY'S LABORATORIES (PTY) LTD.
REDILEV 250/500/750
(FILM-COATED TABLETS)
APPROVED PATIENT INFORMATION LEAFLET**

• REDILEV can cause coordination difficulties. • REDILEV can cause acute damage to the kidneys.
• In the event of any of the following happening to you, contact your medical practitioner without delay:
✓ an increase in the number or severity of seizures (fits)
✓ if you have any symptoms of depression and/or suicidal ideation: A small number of people being treated with antiepileptic medicines such as REDILEV have had thoughts of harming or killing themselves ✓ weakness, feeling light-headed or dizzy or have difficulty breathing, swelling of the face, lip, mouth, eye, tongue and throat, hives and rash as these may be signs of a serious allergic (anaphylactic) reaction ✓ a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome) ✓ a more severe form of rash causing skin peeling in more than 30 % of the body surface (toxic epidermal necrolysis) ✓ flu-like symptoms and a rash on the face followed by an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes (Drug Reaction with Eosinophilia and Systemic Symptoms [DRESS])
• If your treatment has to be stopped, your doctor will recommend to you how to withdraw it gradually.
Children and adolescents: REDILEV should not be used in children younger than 12 years of age.
Other medicines and REDILEV:
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Data indicate that REDILEV does not interact with most other antiepileptic medicines (i.e phenytoin, carbamazepine, valproic acid, phenobarbitone, lamotrigine, gabapentin and primidone), or with oral

DR. REDDY'S LABORATORIES (PTY) LTD.
REDILEV 250/500/750
(FILM-COATED TABLETS)
APPROVED PATIENT INFORMATION LEAFLET

contraceptives, digoxin and warfarin.

Tell your medical practitioner if you are taking any of the following medicines:

- Probenecid, used for gout
- Methotrexate, used for arthritis and certain types of cancer
- Macrogol, used as a laxative. Macrogol should not be taken orally for one hour before and for one hour after taking REDILEV.

Taking REDILEV with food and drink:

You may take REDILEV with or without food.

You should not drink alcohol if you are taking REDILEV.

Pregnancy, breastfeeding and fertility:

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 healthcare professional for advice before taking REDILEV.

The safety of REDILEV in pregnancy and breastfeeding has not been established.

REDILEV is excreted in breast milk.

You should not use REDILEV if you are pregnant or breastfeeding your infant.

Specialist advice should be given to women who are of childbearing potential.

Treatment with REDILEV should be reviewed when a woman is planning to become pregnant.

REDILEV should not be suddenly discontinued as this may lead to breakthrough seizures that could have serious consequences for a woman and the unborn child.

Driving and using machines:

- REDILEV may impair your ability to drive or operate tools or machinery, as it may make you feel sleepy. This is more likely at the beginning of treatment or after an increase in the dose.
- You should not drive or use machines until it is established that your ability to perform such activities is not affected by REDILEV.

3. HOW TO TAKE REDILEV

**DR. REDDY'S LABORATORIES (PTY) LTD.
REDILEV 250/500/750
(FILM-COATED TABLETS)
APPROVED PATIENT INFORMATION LEAFLET**

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

Always take REDILEV exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

REDILEV is used as a chronic treatment. You should continue REDILEV treatment for as long as your doctor has told you. Do not stop your treatment without your doctor's advice as this could increase your seizures. (See **Take special care with REDILEV**).

The recommended dose is to be taken twice a day, once in the morning and once in the evening, at the same time each day.

If you take more REDILEV than you should:

The possible side-effects of an overdose of REDILEV are sleepiness, agitation, aggression, decreased consciousness, inhibition of breathing and coma.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take REDILEV:

Contact your doctor if you have missed one or more doses. Do not take a double dose to make up for a forgotten tablet.

If you stop taking REDILEV:

REDILEV discontinuation should be gradual to avoid an increase of seizures (fits).

If you have any further questions on the use of REDILEV, ask your doctor or pharmacist.

4. POSSIBLE SIDE-EFFECTS

REDILEV can have side-effects.

Not all side-effects reported for REDILEV are included in this leaflet. Should your general health worsen or if

**DR. REDDY'S LABORATORIES (PTY) LTD.
REDILEV 250/500/750
(FILM-COATED TABLETS)
APPROVED PATIENT INFORMATION LEAFLET**

you experience any untoward effects while taking REDILEV, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- weakness, feeling light-headed or dizzy or have difficulty breathing, as these may be signs of a serious allergic (anaphylactic) reaction
- swelling of the face, lips, tongue and throat (Quincke's oedema)
- flu-like symptoms and a rash on the face followed by an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes (Drug Reaction with Eosinophilia and Systemic Symptoms [DRESS])
- symptoms such as low urine volume, tiredness, nausea, vomiting, confusion and swelling in the legs, ankles or feet, as this may be a sign of sudden decrease of kidney function
- signs of serious mental changes or if someone around you notices signs of confusion, somnolence (sleepiness), amnesia (loss of memory), memory impairment (forgetfulness), abnormal behaviour or other neurological signs including involuntary or uncontrolled movements. These could be symptoms of an encephalopathy
- thoughts about suicide or dying, attempts to commit suicide
- depression, hostility or aggression, agitation, anger, anxiety, emotional instability/mood swings, irritability, panic attacks, psychotic symptoms such as hallucinations (seeing or hearing things that are not really there) and delusions (false or strange thoughts or beliefs), other unusual changes in behaviour
- problems with muscle coordination (problems with walking and moving)
- skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge (*erythema multiforme*), a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*), and

DR. REDDY'S LABORATORIES (PTY) LTD.
REDILEV 250/500/750
(FILM-COATED TABLETS)
APPROVED PATIENT INFORMATION LEAFLET

a more severe form causing skin peeling (*toxic epidermal necrolysis*)

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

Tell your doctor if you notice any of the following side-effects. If you have any of these side-effects quite severely or if they cause problems in your ability to function, consult your doctor immediately:

Frequent side-effects:

- nasopharyngitis
- somnolence (sleepiness)
- headache
- anorexia (loss of appetite)
- depression, hostility or aggression, anxiety, insomnia, nervousness or irritability
- convulsion, balance disorder (equilibrium disorder), dizziness (sensation of unsteadiness), lethargy (lack of energy and enthusiasm), tremor (involuntary trembling)
- vertigo (sensation of rotation)
- cough
- abdominal pain, diarrhoea, dyspepsia (indigestion), vomiting, nausea
- rash
- asthenia/fatigue (tiredness)

Less frequent side-effects:

- decreased number of blood platelets, decreased number of white blood cells
- weight decrease, weight increase
- suicide attempt and suicidal ideation, mental disorder, abnormal behaviour, hallucination, anger, confusion, panic attack, emotional instability/mood swings, agitation
- amnesia (loss of memory), memory impairment (forgetfulness), abnormal coordination/ataxia (impaired coordinated movements), paraesthesia (tingling), disturbance in attention (loss of concentration)
- diplopia (double vision), vision blurred

DR. REDDY'S LABORATORIES (PTY) LTD.
REDILEV 250/500/750
(FILM-COATED TABLETS)
APPROVED PATIENT INFORMATION LEAFLET

- elevated/abnormal values in a liver function test
- hair loss, eczema, pruritus
- muscle weakness, myalgia (muscle pain)
- injury
- infection
- decreased number of all blood cell types
- severe allergic reactions (DRESS, anaphylactic reaction [severe and important allergic reaction], Quincke's oedema [swelling of the face, lips, tongue and throat])
- decreased blood sodium concentration
- suicide, personality disorders (behavioural problems), thinking abnormal (slow thinking, unable to concentrate)
- delirium
- encephalopathy
- seizures may become worse or happen more often
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity)
- change of the heart rhythm (electrocardiogram)
- pancreatitis
- liver failure, hepatitis
- sudden decrease in kidney function
- skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (erythema multiforme), a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens–Johnson syndrome), and a more severe form causing skin peeling in more than 30 % of the body surface (toxic epidermal necrolysis)
- rhabdomyolysis (breakdown of muscle tissue) and associated blood creatine phosphokinase increase.

DR. REDDY'S LABORATORIES (PTY) LTD.
REDILEV 250/500/750
(FILM-COATED TABLETS)
APPROVED PATIENT INFORMATION LEAFLET

Prevalence is significantly higher in Japanese patients when compared to non-Japanese patients

- limp or difficulty walking
- repeated unwanted thoughts or sensations or the urge to do something over and over again (obsessive compulsive disorder)
- evidence also suggests a possible predisposition of the Japanese population to neuroleptic malignant syndrome (NMS).

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of REDILEV.

5. HOW TO STORE REDILEV

Store at or below 25 °C in a dry place.

Keep tablets in blisters and blisters in the outer carton until a dose must be taken.

Keep the tablets in the original plastic bottles and keep the bottles well closed.

Store away from heat and direct light.

Do not store in a bathroom, near the kitchen sink, or in other damp places.

Heat or moisture may cause the medicine to break down.

Do not use after the expiry date stated on the label / carton / bottle.

Return all unused medicine to your pharmacist.

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

Store all medicines out of reach of children.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What REDILEV contains:

DR. REDDY'S LABORATORIES (PTY) LTD.
REDILEV 250/500/750
(FILM-COATED TABLETS)
APPROVED PATIENT INFORMATION LEAFLET

The active substance is levetiracetam.
REDILEV 250: Each film-coated tablet contains levetiracetam 250 mg.
REDILEV 500: Each film-coated tablet contains levetiracetam 500 mg.
REDILEV 750: Each film-coated tablet contains levetiracetam 750 mg.
What REDILEV looks like and contents of the pack:
REDILEV 250: Blue, modified capsule-shaped, film-coated tablets debossed with 'LV250' on one side and plain on other side.
REDILEV 500: Yellow, modified capsule-shaped, film-coated tablets debossed with 'LV500' on one side and plain on other side.
REDILEV 750: Peach, modified capsule-shaped, film-coated tablets debossed with 'LV750' on one side and plain on other side.
30, 120, 240 or 500 film-coated tablets in white opaque HDPE bottles with white, opaque, ribbed plastic caps with pulp liners, in an outer printed cardboard carton.
20, 30 or 50 tablets in printed cardboard cartons, as 2, 3, or 5 blister strips of 10 tablets each. The blisters are comprised of clear, transparent PVC (PVdC coated on one side) and silver coloured (paper backed) aluminium foil. Not all strengths and pack sizes may be marketed.
HOLDER OF CERTIFICATE OF REGISTRATION
Dr. Reddy's Laboratories (Pty) Ltd. Block B, 204 Rivonia Road Morningside Sandton 2057
This leaflet was last revised in

**DR. REDDY'S LABORATORIES (PTY) LTD.
REDILEV 250/500/750
(FILM-COATED TABLETS)
APPROVED PATIENT INFORMATION LEAFLET**

02 December 2024
REGISTRATION NUMBER
REDILEV 250: 41/2.5/0460
REDILEV 500: 41/2.5/0461
REDILEV 750: 41/2.5/0462
Access to the corresponding Professional Information
Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website: http://www.drreddys.co.za For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration: Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100