

LACOTOR FILM-COATED TABLETS 50MG / 100MG / 150MG / 200MG

Lacosamide Tablets Ph. Eur (5 mg/100 mg/150mg/200 mg)

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What LACOTOR FILM-COATED TABLETS is used for

LACOTOR FILM-COATED TABLETS contain lacosamide. This belongs to a group of medicines called "antiepileptic medicines". These medicines are used to treat epilepsy.

It is used:

- LACOTOR is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 18 years and older.

How LACOTOR FILM-COATED TABLETS works

Epilepsy is a condition where the patients have repeated fits (seizures). LACOTOR is used for the epilepsy form in which the fits initially affect only one side of the brain but could thereafter extend to larger areas on both sides of the brain (partial onset seizure with or without secondary generalization).

Before you use LACOTOR FILM-COATED TABLETS

- When you must not use it

Do not take LACOTOR FILM-COATED TABLETS:

- if you are allergic to Lacosamide or any of the other ingredients of this medicine. If you are not sure whether you are allergic, please discuss it with

your doctor.

- if you have a certain type of heartbeat problem called second- or third-degree AV block.

Do not take LACOTOR FILM-COATED TABLETS if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

- Before you start to use it

Talk to your doctor before taking LACOTOR FILM-COATED

TABLETS if:

- you have thoughts of harming or killing yourself. A small number of people being treated with antiepileptic medicinal products such as lacosamide have had thoughts of harming or killing themselves. If you have any of these thoughts at any time, tell your doctor straight away.
- you have a heart problem that affects the beat of your heart, and you often have a particularly slow, fast or irregular heartbeat (such as AV block, atrial fibrillation and atrial flutter).
- you have severe heart disease such as heart failure or have had a heart attack.
- you are often dizzy or fall over.

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is not recommended to take LACOTOR FILM-COATED TABLETS if you are pregnant or breast-feeding, as the effects of LACOTOR FILM-COATED TABLETS on pregnancy and the unborn baby or the new-born child are not known. Also, it is not known whether lacosamide passes into breast milk.

Seek advice immediately from your doctor if you get pregnant or are planning to become pregnant. They will help you decide if you should take Lacosamide or not.

Do not stop treatment without talking to your doctor first as this could increase your fits (seizures). A worsening of your disease can also harm your baby.

Paediatric population:

LACOTOR FILM-COATED TABLETS is not recommended for use in paediatric patients below the age of 18 years. This is because it is unknown whether it will work and whether it is safe for children in this age group.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor or pharmacist if you are taking any of the following medicines that affect your heart - this is because LACOTOR FILM-COATED TABLETS can also affect your heart:

- medicines to treat heart problems;
- medicines which can increase the "PR interval" on a scan of the heart (ECG or electrocardiogram) such as medicines for epilepsy or pain called carbamazepine, lamotrigine or pregabalin;
- medicines used to treat certain types of irregular heartbeat or heart failure.

Also tell your doctor or pharmacist if you are taking any of the following medicines - this is because they may increase or decrease the effect of LACOTOR FILM-COATED TABLETS on your body:

- medicines for fungal infections called fluconazole, itraconazole or ketoconazole;
- a medicine for HIV called ritonavir;
- medicines used to treat bacterial infections called clarithromycin or rifampicin;
- a herbal medicine used to treat mild anxiety and depression called St. John's wort.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking LACOTOR FILM-COATED TABLETS.

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How to use LACOTOR FILM-COATED TABLETS

- How much to use

The recommended starting dose of LACOTOR FILM-COATED TABLETS is 50 mg twice a day. Your doctor may also prescribe a starting dose of 100 mg twice a day. Depending on response and tolerability, your doctor may increase your twice daily dose every week by 50 mg. This will be until you reach a maximum recommended daily dose of 400 mg (200 mg twice a day).

- When to use it

- Take LACOTOR FILM-COATED TABLETS twice each day, once in the morning and once in the evening.
- Try to take it at about the same time each day.
- Swallow the LACOTOR FILM-COATED TABLETS tablet with a glass of water.
- You may take LACOTOR FILM-COATED TABLETS with or without food.

You will usually start by taking a low dose each day and your doctor will slowly increase this over a few weeks. When you reach the dose that works for you, this is called the "maintenance dose", you then take the same amount each day. LACOTOR FILM-COATED TABLETS is used as a long-term treatment.

- How long to use it

You should continue to take LACOTOR FILM-COATED TABLETS until your doctor tells you to stop.

Do not stop taking LACOTOR FILM-COATED TABLETS without talking to your doctor, as your epilepsy may come back again or become worse.

If your doctor decides to stop your treatment with LACOTOR FILM-COATED TABLETS, they will tell you how to decrease the dose step by step.

- If you forget to use LACOTOR FILM-COATED TABLETS

- If you missed a dose by a few hours, take it as soon as you remember.
- If it is close to your next dose, do not take the missed tablet anymore. Instead take LACOTOR at the next time you would normally take it.
- Do not take a double dose to make up for a forgotten dose.

- If you use too much LACOTOR FILM-COATED TABLETS (overdose)

If you have taken more LACOTOR FILM-COATED TABLETS than you should, please inform your doctor or go to the emergency department immediately. Take a medicine pack with you. This is so the doctor knows what you have taken. Do not try to drive.

You may experience:

- dizziness
- feeling sick (nausea) or being sick (vomiting)
- fits (seizures)
- heartbeat problems such as a slow, fast, or irregular heartbeat, coma or a fall in blood pressure with rapid heartbeat and sweating.

While you are using LACOTOR FILM-COATED TABLETS

- Things you must do

- Always take this medicine exactly as your doctor tells you. Ask your doctor or pharmacist if you are unsure.
- Tell all doctors, dentists, and pharmacists treating you that you are taking LACOTOR FILM-COATED TABLETS.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not give LACOTOR FILM-COATED TABLETS to other people, even if they have the same symptoms or conditions as you.

- Things to be careful of

LACOTOR FILM-COATED TABLETS can make you dizzy. This can increase the risk of injury or accidental falls. This means that you

should be careful until you get used to the effects of this medicine.

Driving and using machines:

Do not drive, cycle, or use any tools or machines until you know how this medicine affects you. This is because LACOTOR FILM-COATED TABLETS may make you feel dizzy or cause blurred vision.

LACOTOR FILM-COATED TABLETS with alcohol:

As a safety precaution do not take LACOTOR FILM-COATED TABLETS with alcohol.

Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Nervous system side effects such as dizziness may be higher after a single "loading" dose.

Talk to your doctor or pharmacist if you get any of the following:

Very common (may affect more than 1 in 10 people)

- Headache
- Feeling dizzy or sick (nausea)
- Double vision (diplopia)

Common (may affect up to 1 in 10 people)

- Short jerks of a muscle or group of muscles (myoclonic seizures)
- Difficulties in coordinating your movements or walking
- Problems in keeping your balance, shaking (tremor), tingling (paresthesia) or muscle spasms, falling easily and getting bruises
- Troubles with your memory, thinking or finding words, confusion
- Rapid and uncontrollable movements of the eyes (nystagmus), blurred vision
- A spinning sensation (vertigo), feeling drunk
- Being sick (vomiting), dry mouth, constipation, indigestion, excessive gas in the stomach or bowel, diarrhoea
- Decreased feeling or sensitivity, difficulty in articulating words, disturbance in attention

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- Noise in the ear such as buzzing, ringing, or whistling
- Irritability, trouble sleeping, depression
- Sleepiness, tiredness, or weakness (asthenia)
- Itching, rash

Uncommon (may affect up to 1 in 100 people)

- Slow heart rate, palpitations, irregular pulse, or other changes in the electrical activity of your heart (conduction disorder)
- Exaggerated feeling of wellbeing, seeing and/or hearing things which are not there
- Allergic reaction to medicine intake, hives
- Blood tests may show abnormal liver function, liver injury
- Thoughts of harming or killing yourself or attempting suicide: tell your doctor straight away
- Feeling angry or agitated
- Abnormal thinking or losing touch with reality
- Serious allergic reaction which causes swelling of the face, throat, hands, feet, ankles, or lower legs
- Fainting

Not known (frequency cannot be estimated from available data)

- Abnormal rapid heartbeat (ventricular tachyarrhythmia)
- A sore throat, high temperature and getting more infections than usual. Blood tests may show a severe decrease in a specific class of white blood cells (agranulocytosis)
- A serious skin reaction which may include a high temperature and other flu-like symptoms, a rash on the face, extended rash, swollen glands (enlarged lymph nodes). Blood tests may show increased levels of liver enzymes and a type of white blood cell (eosinophilia)
- 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)
- Convulsion

Additional side effects in children

Common (may affect up to 1 in 10 children)

- Runny nose (nasopharyngitis)
- Fever (pyrexia)
- Sore throat (pharyngitis)
- Eating less than usual

Uncommon (may affect up to 1 in 100 children)

- Feeling sleepy or lacking in energy (lethargy)

Not known (frequency cannot be estimated from available data)

- Changes in behaviour, not acting like themselves.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of LACOTOR FILM-COATED TABLETS

- Storage

- Do not store above 30°C.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

- Disposal

- Do not throw away any medicines via wastewater or household waste.
- Ask your pharmacist how to throw away medicines you no longer use.
- These measures will help to protect the environment.

Product Description

- What it looks like

50 mg Film coated tablet: Light pink, oval, film-coated tablets debossed with

'E1' on one side and plain on the other side.

100 mg Film coated tablet: Yellow, oval, film-coated tablets debossed with 'E2' on one side and plain on the other side.

150 mg Film coated tablet: Beige, oval, film-coated tablets debossed with 'E3' on one side and plain on the other side.

200 mg Film coated tablet: Blue, oval, film-coated tablets debossed with 'E4' on one side and plain on the other side.

LACOTOR FILM-COATED TABLETS is available in blisters in cartons of 10 tablets, 30 tablets and 100 tablets.

- Ingredients

- Active ingredient
Lacosamide Ph. Eur.

- Inactive ingredients
Tablet core 50 mg/100mg/150mg & 200mg:

- Cellulose Microcrystalline
- Crospovidone
- Hydroxypropylcellulose, low-substituted
- Hydroxypropylcellulose
- Silica colloidal anhydrous
- Magnesium stearate

• Tablet film coating 50mg:

- Polyvinyl alcohol
- Titanium dioxide
- Macrogol 3350
- Talc
- Iron oxide red
- Iron oxide black
- FD&C Blue Indigo Carmine aluminium lake

• Tablet film coating 100mg:

- Polyvinyl alcohol
- Titanium dioxide
- Macrogol 3350
- Talc
- Iron oxide Yellow
- Iron oxide red

• Tablet film coating 150mg:

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- Polyvinyl alcohol
- Titanium dioxide
- Macrogol 3350
- Talc
- Iron oxide Yellow
- Iron oxide red
- Iron oxide black

- Tablet film coating 200mg:
 - Polyvinyl alcohol
 - Titanium dioxide
 - Macrogol 3350
 - Talc
 - FD&C Blue Indigo Carmine
 - aluminium lake

- MAL Numbers:

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MALXXXXXXXXXX

**LACOTOR FILM-COATED
TABLETS 100MG**
MALXXXXXXXXXX

**LACOTOR FILM-COATED
TABLETS 150MG**
MALXXXXXXXXXX

**LACOTOR FILM-COATED
TABLETS 200MG**
MALXXXXXXXXXX

Manufacturer

TORRENT PHARMACEUTICALS
LTD.
Bhud & Makhnu Majra, Baddi 173205,
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Product Registration Holder

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