

EXCARB TABLETS

Eslicarbazepine Acetate (200mg/400mg/600mg/800mg)

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What Excarb is used for

Eslicarbazepine acetate is used

- On its own (monotherapy) in adult patients with newly diagnosed epilepsy.
- With other antiepileptic medicines (adjunctive therapy), in adult, adolescents and children patients above 6 years of age who are experiencing seizures that affect one part of the brain (partial seizure). These seizures may or may not be followed by a seizure affecting all of the brain (secondary generalisation).

How Excarb works

Eslicarbazepine acetate are extensively converted to eslicarbazepine, which is considered to be responsible for therapeutic effects. Both eslicarbazepine acetate and its metabolites stabilise the inactivated state of voltage-gated sodium channels, precluding their return to the activated state and thereby preventing repetitive neuronal firing.

Before you use Excarb

- When you must not use Excarb

- If you are allergic to eslicarbazepine acetate, to other carboxamide derivatives (e.g. carbamazepine or oxcarbazepine, medicines used to treat epilepsy) or to any of the other ingredients of this medicine.
- If you suffer from a certain type of heart rhythm disorder (second or third degree atrioventricular (AV) block).

- Before you start to use Excarb

Please tell your doctor:

- If you have kidney problems. Your doctor may need to adjust the dose. Excarb is not recommended in patients with severe renal disease.

- If you have liver problems. Excarb is not recommended in patients with severe liver problems.
- If you are taking any medicine which can cause an abnormality on the ECG (electrocardiogram) called increased PR interval. If you are not sure if the medicines you are taking could have this effect, discuss with your doctor.
- If you suffer from a heart disease such as heart failure, heart attack or have any heart rhythm disorder.
- If you suffer from seizures that begin with a widespread electric discharge that involves both sides of the brain.

Children

Excarb is not to be given to children aged 6 years and below.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is just in case any of them interfere with how Excarb works or how Excarb interferes with their effect.

Tell your doctor if you are taking:

- Phenytoin (a medicine used to treat epilepsy) since your dose may need to be adjusted;
- Carbamazepine (a medicine used to treat epilepsy) since your dose may have to be adjusted and the following side effects of Excarb may occur in higher frequency: seeing double, abnormal coordination and dizziness;
- Hormonal contraceptives (such as the contraceptive pill) since Excarb may make these less effective;
- Simvastatin (a medicine used to lower cholesterol levels) since your dose may have to be adjusted;
- Rosuvastatin, a medicine used to lower cholesterol level;
- The blood thinner - warfarin;
- Tricyclic antidepressants e.g. amitriptyline;
- Do not take oxcarbazepine (a medicine used to treat epilepsy) with Excarb, as it is not known whether it is safe to take these medicines together.

How to use Excarb

- How much to use

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dose for adults

Dose when you start treatment 400 mg once daily for one or two weeks, before increasing to the maintenance dose. Your doctor will decide whether you will be given this dose for one or two weeks.

Maintenance dose

The usual maintenance dose is 800 mg once daily. Depending on how you respond to Excarb, your dose may be increased to 1,200 mg once daily. If you are taking Excarb on its own your doctor may consider you can benefit of a dose of 1,600 mg once daily.

Patients with kidney problems

If you have kidney problems you will usually be given a lower dose of Excarb. Your doctor will work out the correct dose for you. Excarb is not recommended if you have severe kidney problems.

Elderly (over 65 years of age)

If you are elderly and taking Excarb on its own, the dose of 1,600 mg is not a suitable dose for you.

Dose for children

Children above 6 years of age

Dose when you start treatment. The starting dose is 10 mg per kg body weight taken once a day for one or two weeks, before increasing to the maintenance dose.

Maintenance dose

Depending on the response to Excarb, the dose may be increased by 10 mg per kg body weight, at intervals of one or two weeks, up to 30 mg per kg body weight. The maximum dose is 1,200 mg once daily.

Children with ≥ 60 kg

Children with 60 kg or more body weight should take the same dose as adults. Other form of this medicine, like oral suspension, maybe more suitable for children. Ask your doctor or pharmacist.

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Method and route of administration

Excarb is for oral use. Swallow the tablet with a glass of water. It may be taken without food. Excarb tablet can be split, except for the 400 mg tablet. Do not crush or mix the tablet with any other liquids.

- When to use it

Always take this medicine as directed by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure.

- How long to use it

Take this medicine exactly as your doctor or pharmacist has told you. Do not stop taking Excarb abruptly. If you have further question regarding the usage of this medication. Consult your doctor or pharmacist

- If you forget to use Excarb

If you forget to take a tablet, take it as soon as you remember and carry on as usual. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you accidentally take more Excarb than you should, you are potentially at risk of having more seizures; or you may feel like your heartbeat is irregular or faster. Contact a doctor or go to a hospital immediately if you experience any of the above symptoms. Take the medicine pack with you. This is so the doctor knows what you have taken.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. There are no data from the use of eslicarbazepine acetate in pregnant women. Research has shown an increased risk of birth defects in children of women taking antiepileptic medicines. On the other hand, effective antiepileptic therapy must not be interrupted since the worsening of the disease is harmful to both the mother and the unborn child. Do not breast-feed while you are taking Excarb. It is not known whether it passes into breast milk.

Excarb may make hormonal contraceptives such as the contraceptive pill less effective. Therefore, it is recommended that you use other forms of safe and effective contraception, when taking Excarb up to the end of the current menstrual cycle after stopping treatment.

While you are using it

- Thing you must do

Contact your doctor immediately:

- If you have blistering or peeling of the skin and/or mucous membranes, rash, swallowing or breathing problems, swelling of your lips, face, eyelids, throat or tongue. These could be signs of an allergic reaction.
- If you suffer from confusion, worsening of seizures or decreased consciousness which can be signs of low blood salt levels.

A small number of people being treated with antiepileptics have had thoughts of harming or killing themselves. If at any time you have these thoughts, when taking Excarb contact your doctor immediately. Excarb may make you feel dizzy and/or drowsy, particularly at the beginning of treatment. Take special care when taking Excarb to avoid accidental injury, such as fall. If you develop a serious rash or another skin symptoms, stop taking Excarb and contact your doctor or seek medical attention immediately.

- Things you must not do

Do not stop taking your tablets suddenly. If you do, you are at risk of having more seizures. Your doctor will decide how long you should take Excarb. Should your doctor decides to stop your treatment with Excarb your dose will usually be reduced gradually. It is important that your treatment is completed as advised by your doctor or your symptoms may get worse. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- Things to be careful of

Driving and using machines

Excarb may make you feel dizzy, drowsy and affect your vision, particularly at the

beginning of treatment. If this happens to you, do not drive or use any tools or machines.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects can be very serious. If they happen to you stop taking Excarb and tell a doctor or go to a hospital immediately, as you may need urgent medical treatment: blistering or peeling of the skin and/or mucous membranes, rash, swallowing or breathing problems, swelling of your lips, face, eyelids, throat or tongue. These could be signs of an allergic reaction.

Very common

Feeling dizzy or sleepy.

Common

- Feeling unsteady or having a sensation of spinning or floating;
- Feeling sick or vomiting;
- Headache;
- Diarrhoea;
- Seeing double or blurred vision;
- Difficulty in concentration;
- Feeling low in energy or tired;
- Shaking;
- Skin rash;
- Blood tests showing that you have low levels of sodium in your blood;
- Decrease of appetite;
- Difficulty in sleeping;
- Difficulty in coordinating movements (ataxia).
- Weight increase.

Uncommon

- Clumsiness;
- Allergy;
- Constipation;
- Seizures;
- Underactive thyroid gland. Symptoms include decreased level of thyroid hormone levels (seen in blood tests), cold intolerance, large tongue, thin and brittle fingernails or hair and low body temperature;
- Liver problems;
- High blood pressure or severe increase in blood pressure;
- Low blood pressure or a fall in blood pressure on standing up;

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- Blood tests showing that you have low levels of salts (including chloride) in your blood or a reduction in red blood cells;
- Dehydration;
- Eye movement changes, fuzzy vision or red eye;
- Having falls;
- Thermal burn;
- Poor memory or forgetfulness;
- Crying, feeling depressed, nervous or confused, lack of interest or emotion;
- Inability to speak or write or understand spoken or written language;
- Agitation;
- Attention deficit/ hyperactivity disorder;
- Irritability;
- Mood changes or hallucinations;
- Difficulty in speaking;
- Nosebleed;
- Chest pain;
- Tingling and/or feeling numb in any part of your body;
- Migraine;
- Burning sensation;
- Abnormal sense of touch;
- Disturbances in the sense of smell;
- Ringing in the ears;
- Hearing difficulty;
- Swelling in your legs and arms;
- Heart burn, stomach upset, abdominal pain, abdominal bloating and discomfort or dry mouth;
- Charcoal (dark) stool;
- Inflamed gums or toothache;
- Sweating or having dry skin;
- Itching
- Skin changes (e.g. red skin);
- Hair loss;
- Urinary tract infection;
- Feeling generally weak, unwell or having chills;
- Weight loss;
- Muscle pain, pain in limbs, muscular weakness;
- Bone metabolism disorder;
- Increased bone proteins;
- Flushing, cold limbs;
- Slower or irregular heart beat;
- Feeling extremely sleepy;
- Sedation;
- Neurological movement disorder where your muscles contract causing twisting and repetitive movements or abnormal postures. Symptoms include tremors, pain, cramping;

- Medicine toxicity;
- Anxiety;

Not known side effects are:

- Reduction in blood platelets which increases risk of bleeding or bruising;
- Severe pain in the back and stomach (caused by inflammation of the pancreas);
- Reduction in white blood cells which makes infections more likely;
- Reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, red and swollen eyes and can be preceded by fever and/or flu-like symptoms (Stevens- Johnson syndrome/toxic epidermal necrolysis);
- Initially flu-like symptoms, rash on the face then widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome);
- Serious allergic reaction which causes swelling of the face, throat, hand, feet, ankles, or lower legs;
- Urticaria (skin rash with itching). The use of Excarb is associated with an abnormality in ECG (electrocardiogram) called increase in PR interval. Side effects associated with this ECG abnormality (e.g. fainting and slowing of heart beat) may occur. There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures with structurally related antiepileptics medicines like carbamazepine and oxcarbazepine. Check with your doctor or pharmacist, if you are on long-term antiepileptic treatment, have a history of osteoporosis, or take steroids.

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 nppra.gov.my [Consumers →Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Excarb

- Storage

Store below 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

- 200 mg tablet: white to off-white, oblong, uncoated tablets debossed with 'V1' on one side and break line on the other side.
- 400 mg tablet: white to off-white, circular, biconvex, uncoated tablets debossed with 'V2' on one side and plain on the other side.
- 600 mg tablet: white to off-white, oblong, uncoated tablets debossed with 'V3' on one side and break line on the other side.
- 800 mg tablet: white to off-white, oblong, uncoated tablets debossed with 'V7' on one side and break line on the other side.

Excarb is available in blisters as cartons of 10 tablets, 30 tablets and 100 tablets.

- Ingredients

Excarb 200mg/400mg/600mg/800mg

Active ingredients

The active ingredient of Excarb is eslicarbazepine acetate

Inactive ingredients

The inactive ingredients are microcrystalline cellulose, croscarmellose sodium, povidone (K-30), colloidal silicon dioxide, magnesium stearate

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- MAL number

Excarb Tablets 200mg

MAL*****

Excarb Tablets 400mg

MAL*****

Excarb Tablets 600mg

MAL*****

Excarb Tablets 800mg

MAL*****

Manufacturer

TORRENT PHARMACEUTICALS
LTD.

Plot No. Z/104 TO 106, Dahej Sez
Part-II, Tal - Vagra, Dist-Bharuch -
392130, Gujarat state, India.

Product Registration Holder

Laboratories Torrent (Malaysia)
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11/04/2025

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