

# CELTOR TABLETS

Levodopa, Carbidopa and Entacapone (50mg + 12.5mg + 200mg, 100mg + 25mg + 200mg)

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## What CELTOR is used for

It is used for the treatment of Parkinson's disease.

## How CELTOR works

Parkinson's disease is caused by low levels of a substance called dopamine in the brain. Levodopa increases the amount of dopamine and hence reduces the symptoms of Parkinson's disease. Carbidopa and Entacapone improve the anti-Parkinson effects of Levodopa.

## Before you use CELTOR

### - When you must not use it

Do not take CELTOR:

- If you are allergic to levodopa, carbidopa or entacapone, or any of the other ingredients of this medicine.
- If you have narrow-angle glaucoma (an eye disorder).
- If you have a tumour of the adrenal gland.
- If you are taking certain medicines for treating depression (combinations of selective MAO-A and MAO-B inhibitors or non-selective MAO-inhibitors).
- If you have ever had neuroleptic malignant syndrome (NMS - this is a rare reaction to medicines used to treat severe mental disorders).
- If you have ever had non-traumatic rhabdomyolysis (a rare muscle disorder).
- If you have a severe liver disease.

### *Pregnancy and lactation*

Do not take CELTOR if you are pregnant or plan to become pregnant or think you might be pregnant.

Do not take CELTOR if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

### - Before you start use it

Talk to your doctor before taking CELTOR if you suffer from or you ever had:-

- A heart attack or any other diseases of the heart including cardiac arrhythmias (irregular heartbeat), or of the blood vessels.
- A liver problem, because your dose may need to be adjusted.
- Kidney or hormone-related diseases.
- Stomach ulcers or convulsions.
- If you experience prolonged diarrhoea consult your doctor as it may be a sign of inflammation of the colon.
- Any form of severe mental disorder like psychosis.
- Chronic wide-angle glaucoma, because your dose may need to be adjusted and the pressure in your eyes may need to be monitored.

### - Taking other medicines

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

Do not take Levodopa / Carbidopa / Entacapone if you are taking certain medicines for treating depression (combinations of selective MAO-A and MAO-B inhibitors, or non-selective MAO inhibitors).

Do not take Levodopa / Carbidopa / Entacapone if you are taking medicine containing dopamine receptor antagonists (e.g. some antipsychotics and antiemetics), phenytoin and papaverine. This medicine may reduce the effect of levodopa.

Levodopa / Carbidopa / Entacapone may increase the effects and side effects of certain medicines.

These include:

- Medicines used to treat depression such as moclobemide, amitryptiline, desipramine, maprotiline, venlafaxine and paroxetine.
- Rimiterole and isoprenaline, used to treat respiratory diseases.
- Adrenaline, used for severe allergic reactions.
- Noradrenaline, dopamine and dobutamine, used to treat heart diseases and low blood pressure.

- Alpha-methyldopa, used to treat high blood pressure.
- Drugs used to treat Parkinson's disease.
- Celtor may make it harder for you to digest iron. Therefore, do not take Celtor and iron supplements at the same time. After taking one of them, wait at least 2 to 3 hours before taking the other.

## How to use CELTOR

### - How much to use

Your doctor will tell you exactly how many tablets of CELTOR to take each day. Only one tablet should be taken as instructed. Patients receiving less than 70-100mg carbidopa may experience nausea and vomiting. Total daily dose greater than 200mg carbidopa is limited and maximum dose of entacapone should be 2000mg.

The tablets are not intended to be split or broken into smaller pieces.

You should take only one tablet each time.

### - When to use it

May be taken with or without food.

You can take CELTOR with or without food. Swallow CELTOR with a glass of water.

Take CELTOR at about the same time each day.

### - How long to use it

Ask your doctor or pharmacist how long you can take it. Do not initiate or stop the treatment without consulting your doctor. Stopping your treatment with CELTOR may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

### - If you forget to use it

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed.

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

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## - If you use too much (overdose)

In case of an overdose you may feel confused or agitated, your heart rate may be slower or faster than normal or the color of your skin, tongue, eyes or urine may change. Contact your doctor, pharmacist, or hospital.

## While you are using it

### - Things you must do

- Take your medicine exactly as your doctor has told you.
- Take CELTOR at about the same time each day.
- Tell all the doctors, dentists and pharmacists treating you that you are taking CELTOR.
- Tell your doctor immediately if you become pregnant while taking this medication.

### - Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give CELTOR to anyone else, even if they have the same symptoms or condition as you.

### - Things to be careful of

#### Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

## Side effects

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

### Very common side effects:

- Chromaturia (harmless reddish-brown discolouration of urine).
- Diarrhoea and nausea.
- Uncontrolled movements (dyskinesias).
- Muscle, musculoskeletal and connective tissue pain.

### Common side effects:

- Anaemia (lack of red blood cells).
- Decreased in weight.
- Decreased in appetite.
- Depression.

- Hallucinations.
- Confusion.
- Abnormal dreams.
- Anxiety.
- Insomnia (inability to sleep).
- Worsening of Parkinson's symptom (bradykinesia (slowness of movement)).
- Tremor.
- Dystonia (uncontrollable and painful muscle cramps).
- Mental impairment (e.g. memory impairment, dementia).
- Somnolence, dizziness, headache.
- Blurred vision.
- Ischemic heart disease events other than myocardial infarction (e.g. angina pectoris) and irregular heart rhythm.
- Orthostatic hypotension (low blood pressure that happens when you stand up from sitting or lying down) and hypertension.
- Dyspnoea (shortness of breath).
- Constipation, vomiting, dyspepsia (indigestion), abdominal pain and discomfort.
- Dry mouth.
- Rash and hyperhidrosis (excessive sweating).
- Muscle spasms and arthralgia (joint pain).
- Urinary tract infection.
- Chest pain, peripheral oedema (accumulation of fluid causing swelling usually in lower limbs), fall, gait disturbance, asthenia (lack of energy), fatigue.

### Uncommon side effects:

- Thrombocytopenia (low blood platelet count).
- Psychosis, agitation.
- Myocardial infarction (heart attack).
- Gastrointestinal haemorrhage (all forms of bleeding from the mouth to the rectum).
- Colitis (inflammation of the inner lining of the colon), dysphagia (difficulty in swallowing).
- Liver function test abnormal\*
- Discolorations other than urine (e.g. skin, nail, hair, sweat).
- Urinary retention.
- Malaise (a general feeling of discomfort, illness, or unease whose exact cause is difficult to identify).

### Other side effects reported:

- Rhabdomyolysis (breakdown of damaged skeletal muscle).
- Urticaria (raised, itchy rash that appears on the skin).
- Angioedema (severe swelling beneath the skin).
- Hepatitis with mainly cholestatic features (affecting production of bile from liver).
- Neuroleptic malignant syndrome (life-threatening reaction that occasionally occurs in response to neuroleptic or antipsychotic medication).
- Suicidal behaviour.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

These are not all the possible side effects of CELTOR. For a complete list, ask your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public→Reporting Medicinal problems / Side Effects / AEFI / Vaccine Safety).

## Storage and Disposal of CELTOR

### - Storage

Store below 30°C. Protect from light and moisture.

### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## Product Description

### - What it looks like

**CELTOR TABLETS (50mg + 12.5mg + 200mg)**

Light brown to grayish red colored, round, biconvex, film coated tablets with debossed "50" on one side and plain on other side.

# CELTOR TABLETS

Levodopa, Carbidopa and Entacapone (50mg + 12.5mg + 200mg, 100mg + 25mg + 200mg)

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## **CELTOR TABLETS (100mg+ 25mg + 200mg)**

Light brown to grayish red colored, oval shaped, film coated tablets with debossed "100" on one side and plain on other side.

### Ingredients

Active ingredients:

- Levodopa.
- Carbidopa.
- Entacapone.

Inactive ingredients:

- Microcrystalline Cellulose.
- Povidone K-30.
- Crospovidone XL10.
- Magnesium Stearate.
- Sodium citrate.
- Titanium Dioxide.
- Hypromellose 2910.
- Polyethylene Glycol 6000.
- Ferric Oxide Red.
- Ferric Oxide Yellow.
- Polysorbate 80.

- MAL number(s):

**CELTOR TABLETS (50mg + 12.5mg + 200mg)**  
MAL\*\*\*\*\*

**CELTOR TABLETS (100mg+ 25mg + 200mg)**  
MAL\*\*\*\*\*

### **Manufacturer**

Torrent Pharmaceuticals LTD.  
Indrad 382 721, District: Mehsana,  
India.

### **Product Registration Holder**

Laboratories Torrent (Malaysia) Sdn.  
Bhd.  
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### **Date of revision**

15/05/2018

### **Serial Number**

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