CARBATOL-CR TABLET

Carbamazepine (200mg, 400mg)

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What Carbatol-CR is used for

- Carbatol-CR is indicated in the treatment of various epileptic seizures.
- To control mania (mental disturbance) and mood disorder.
- To control sudden, repeated attacks of facial pain, known as trigeminal neuralgia.
- Used in alcohol withdrawal syndrome.

How Carbatol-CR works

Carbamazepine belongs to a group of medicines called anticonvulsants.

These medicines are thought to work by regulating the way messages in the brain are passed on by nerves so that seizures do not happen. Carbamazepine also regulates other nerve functions in the body.

Before you use Carbatol-CR

- *When you must not use it*

Do not take Carbatol-CR if:

- You are allergic (hypersensitive) to carbamazepine or any of the other ingredients in this medicine.
- This medicine should not be used if you have atrioventricular block (a type of heart block), a history of bone marrow depression or acute intermittent porphyria (a rare group of blood disorders).

Pregnancy and lactation

Do not take Carbatol-CR if you are pregnant, trying to get pregnant or think you may be pregnant.

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

- *Before you start use it*

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

- Heart problems.
- Liver or kidney problems.
- Problems with your blood in the past that were caused by medicines you were taking.
- A mental disorder such as depression.
- Have had thoughts of harming or killing yourself.
- Increased fluid pressure in the eye called intraocular pressure.

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription because these might interact with carbamazepine. It is particularly important for carbamazepine, since many other medicines interact with it. For example:

- Hormone medicine (levothyroxine, gestrinone, tibolone, danazol)
- Antihistamines (loratadine, terfenadine)
- Anticonvulsants (clobazam, clonazepam, ethosuximide, primidone, valproic acid, lamotrigine, tiagabine, topiramate, oxcarbazepine, phenobarbitone, phenytoin)
- Antidepressions (alprazolam, imipramine, amitriptyline, nortriptyline, clomipramine, viloxazine, fluoxetine, fluvoxamine, nefazodone)
- Corticosteroids (prednisolone, dexamethasone).
- Immunosuppressants (cyclosporin)
- Heart medicine (digoxin, diltiazem, verapamil, statins)
- Antibiotics (erythromycin, clarithromycin, doxycycline)
- Pressure medicine (felodipine and isradipine)
- Medicine to treat HIV/AIDS (indinavir, saquinavir, ritonavir)
- Antipsychotics (haloperidol, clozapine, olanzapine, risperidone, thioridazine)
- Drugs detoxification medicine (methadone)
- Pain killers (tramadol, paracetamol or acetaminophen, dextropropoxyphene)
- Oral contraceptives (products containing oestrogens dan / atau progestogens),
- Cancer medicine (toremifene, cisplatin, doxorubicin)
- Asthma medicine (theophylline)
- Oral anticoagulant (warfarin)
- Antifungal medicine (itraconazole, ketoconazole, fluconazole)
- Antituberculosis (isoniazid, rifampicin)
- Skin medicine (isotretinoin)
- Diuretrics (hydrochlorothiazide, furosemide)
- Bipolar disorder medicine (lithium)
- Monoamine Oxidase Inhibitors (MAOIs). MAOIs need to be discontinued for minimum of 14 days before taking Carbatol-CR.
- Muscle relaxant (pancuronium)
- Medicine to treat heartburn and peptic ulcer (cimetidine).
- Medicine to treat eye disease known as glaucoma (acetazolamide)
- Vitamin B3 supplements (nicotinamide)
- Antimalarial medicine (mefloquine)
- Herbal remedy, St John's wort (medicine used for emotion depression disorders)

How to use Carbatol-CR

- *How much to use*

Adults and children over 15years of age:

Monotherapy treatment with Carbatol-CR, 100-200mg taken once or twice a day. Doctor will probably increase the dose to 800mg-1200mg daily for the best response.

Children aged 6-15 years of age:

The usual dose in children is 10-20mg/kg daily in divided doses.

Children with 6-10 years of age:

400-600mg daily.

Children with 11-15 years of age:

600-1000mg.

Trigeminal Neuralgia:

The starting dose is 200-400mg daily and should be increased periodically until there is no pain (usually at 200mg, 3-4 times daily).

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Elderly: 100mg twice daily.

Alcohol withdrawal Syndrome:
200mg 3-4 times daily. This dose can be increased up to 400mg taken three times per day in severe cases.

Mania and Prevention of manic-depressive psychosis:
Initial starting dose is 400mg daily, in divided doses, which can be increased gradually until symptoms are controlled or a total of 1600mg given in divided doses is reached. The usual dosage range is 400-600mg daily, given in divided doses.

- *When to use it*

Try to take Carbatol-CR tablet at the same time each day. Carbatol-CR should not be chewed but should be swallowed with a little liquid, before, during or between meals.

- *How long to use it*

Continue taking Carbatol-CR for the duration that doctor recommends.

- *If you forget to use it*

Consult your doctor or pharmacist about what to do if you forget to use this medicine.

Take the missed dose as soon as you remember. If it is almost time for the next dose, ignore the missed dose and then continue taking the medication according to the schedule as usual. Do not take a double dose to replace the missed dose.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department at the nearest hospital, if an overdose has been used. This should be done even if there is no symptom of poisoning or discomfort. You may need immediate medical attention.

An overdose of this medicine may cause:

- Agitation.
- Disorientation.
- Vomiting.
- Difficulty breathing.
- Fast and irregular heartbeat.
- Blurred vision.
- Convulsion.
- Slurred speech.

While you are using it

- *Things you must do*

- Take Carbatol-CR only with a doctor's prescription.
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists that are treating you that you are taking Carbatol-CR.
- Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

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

- *Things to be careful*

Driving or operate machinery:
This medicine may interfere with your ability to drive or operate machinery. If this medication causes you to feel nauseous, dizzy, tired, or have a headache, do not drive or operate machinery and contact your doctor immediately.

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

Central nervous system (CNS):
Commonly seen side effects are dizziness, headache, ataxia (lack of muscle control or coordination of voluntary movements, such as walking or picking up object), drowsiness, fatigue, diplopia (double vision), blurred.

Skin and appendages:

- Allergic skin reactions
- Urticaria (hives)
- Exfoliative dermatitis and erythroderma (severe inflammation of the entire skin surface)
- Lupus erythematosus-like syndrome (autoimmune disorder)
- Pruritus (itch)
- Stevens Johnson syndrome (type of severe skin reaction)
- Toxic epidermal necrolysis (life-threatening skin disorder)
- Photosensitivity
- Erythema multiforme nodosum (skin immune reaction that an infection or medication can trigger)
- Alterations in skin pigmentation
- Purpura (condition of red or purple discolored spots on the skin that do not blanch on applying pressure)
- Acne
- Sweating
- Hair loss.

Blood:

- Leucopenia (decrease in the number of white blood cells)
- Thrombocytopenia (abnormally low levels of platelets)
- Eosinophilia (high eosinophils - specialized cell of the immune system)
- Leucocytosis (condition in which there is decrease in the number of white blood cells)
- Lymphadenopathy (enlargement of lymph nodes)
- Folic acid deficiency
- Agranulocytosis (decrease in the number of granulocytes which is a type of white blood cell)
- Aplastic anaemia (condition that occurs when your body stops producing enough new blood cells)
- Pure red cell aplasia (rare disorder of blood production)
- Egaloblastic anaemia (red blood cells that are larger than normal)
- Porphyria (rare metabolic disorder)
- Reticulocytosis (condition where there is an increase in reticulocytes, immature red blood cells)
- Haemolytic anaemia (disorder in which red blood cells are destroyed faster than they can be made)

Liver:

- High levels of Gamma-Glutamyl Transferase (GGT) in the blood may be a sign of liver disease or damage to the bile ducts.
- Elevated alkaline phosphatase (a sign of liver disease)
- Elevated transaminases (a sign of liver disease)
- Inflammation of the liver
- Jaundice
- Liver failure.

Gastro-intestinal tract:

- Nausea
- Vomiting

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- Dryness of the mouth with suppositories rectal irritation may occur.
- Diarrhoea or constipation
- Abdominal pain
- Glossitis (inflammation of the tongue)
- Stomatitis (inflammation of the mouth and lips)
- Inflammation of the pancreas

Hypersensitivity reactions:

- A delayed multi-organ hypersensitivity disorder with fever
- Skin rashes
- Inflammation of the blood vessels
- Lymphadenopathy (enlargement of lymph nodes)
- Cancer
- Arthralgia (joint pain)
- Leucopenia (decrease in the number of white blood cells)
- Eosinophilia (high eosinophils - specialized cell of the immune system)
- Hepato-splenomegaly (a disorder where both the liver and spleen swell beyond their normal size)
- Abnormal liver function tests,
- Serous inflammation of the linings of the brain with sudden muscle spasm and peripheral eosinophilia.
- Anaphylactic reaction (severe allergic reaction).
- Angioedema (angioedema is the swelling of the deeper layers of the skin, caused by a build-up of fluid)

Cardiovascular system:

- The adverse reactions are rare including disturbances of heart system, hypertension (high blood pressure) or hypotension (low blood pressure)
- Bradycardia (slow heart rate)
- Arrhythmias (irregular heartbeat)
- Heart block
- Collapse
- Congestive heart failure
- Aggravation of heart disease
- Thrombophlebitis or thromboembolism (blood clots in the veins).

Endocrine system and metabolism:

- Oedema (fluid retention which cause swelling in certain areas of the body, for example, the legs, feet, ankles, or hands)
- Weight increase
- Hyponatraemia (low level of sodium in the blood)
- Reduced plasma osmolality due to an antidiuretic hormone (ADH)-like effect, leading in rare cases to water intoxication accompanied by lethargy, vomiting, headache, mental confusion, neurological abnormalities.

Urogenital system:

- Interstitial nephritis (kidney disorder)
- Kidney failure
- Kidney dysfunction e.g. albuminuria (too much protein albumin found in urine), haematuria (presence of blood in the urine), oliguria (less urine output) and azotaemia (high blood urine nitrogen level).
- Urinary frequency
- Urinary retention
- Sexual disturbances / impotence.

Sense organs:

- Taste disturbances
- Lens opacities
- Conjunctivitis (inflammation of the outermost layer of the white part of the eye and the inner surface of the eyelid)
- Hearing disorders, e.g. Tinnitus (ringing in the ears), hyperacusis (everyday sounds seem much louder than they should), hypoacusis (loss of hearing), change in pitch perception.

Musculoskeletal system:

- Arthralgia (joint pain)
- Muscle pain or cramp.

Respiratory tract:

- Fever
- Dyspnoea (difficult breathing)
- Pneumonitis (inflamed lungs)
- Pneumonia (an infection in one or both lungs).

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 Carbatol-CR

- *Storage*

Store below 30ºC, protected from 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*

CARBATOL-CR 200 TABLET:
Light brown coloured, round, biconvex film coated tablets with bisecting line on one side of tablet and other side plain.

CARBATOL-CR 400 TABLET:
Light brown coloured, round, biconvex film coated tablets with bisecting line on one side of the tablet and other side plain.

- *Ingredients*

Active ingredient:

- Carbamazepine.

Inactive ingredients:

- Croscarmellose Sodium.
- Carbretard Pellets.
- Acetone.
- Methylene Chloride.
- Microcrystalline Cellulose (Avicel pH102).
- Talc.
- Ferric Oxide Red.
- Sodium Starch Glycolate.
- Eudragit RSPO.
- TRC Coat A.
- Purified water.

- *MAL number(s):*

Carbatol CR-200 Tablet:
MAL06071037AZ

Carbatol-CR 400 Tablet:
MAL06071038AZ

Manufacturer

Torrent Pharmaceuticals Limited
Indrad 382 721, Tal: Kadi,
City: Indrad, Dist. Mehsana,
India

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Product Registration Holder

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