

CERATOR EXTENDED-RELEASE TABLET

Pentoxifylline (400 mg)

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What CERATOR is used for

CERATOR contains a medicine called Pentoxifylline. This belongs to a group of medicines called peripheral vasodilators. It works by increasing the blood flow.

CERATOR is indicated for:

- Disorder of brain blood circulation as a consequence of cerebral arteriosclerosis (thickening and hardening of the walls of the blood vessels in the brain) e.g. lack/ difficulty in concentration, vertigo, forgetfulness/ impairment of memory
- Peripheral blood vessel disease (poor circulation to the arms and legs).
- Intermittent claudication (pain on walking or at rest caused by poor circulation to the legs)
- Trophic disturbances (e.g. leg ulcers and gangrene).

How CERATOR works

Pentoxifylline works by reducing blood viscosity and improving peripheral blood flow thus enhance peripheral tissue oxygenation.

Before you use CERATOR

- When you must not use it

⊗ If you are allergic (hypersensitive) to Pentoxifylline, other methyl xanthines, or to any of the other ingredients of CERATOR.

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

- ⊗ If you have heart problems or have recently had heart attack
- ⊗ If you have severe palpitations (very fast and uneven heartbeats)
- ⊗ If you have had a stroke with bleeding in the brain (cerebral hemorrhage)
- ⊗ If you have had bleeding in the eye (retinal hemorrhage)
- ⊗ If you are Pregnant and breast-feeding
⇒ You should not use CERATOR if you are pregnant. CERATOR may

be used only if the doctor decides that the anticipated benefit of the treatment outweighs the potential risks to the fetus. If you are planning to become pregnant or think that you may be pregnant, speak to your doctor to know if CERATOR is suitable for you.

⇒ Do not take CERATOR if you are breast-feeding or planning to breast-feed. Talk to your doctor or pharmacist before using CERATOR. This is because very small amounts may pass into the mother's milk.

Do not use this medicine if any of the above applies to you. If you are not sure, get advice from your doctor or pharmacist before taking CERATOR.

- Before you start to use it

Please inform your doctor or pharmacist if you have the following condition:

- Hypotension (low blood pressure) or you have severe coronary artery disease (heart disease).
~ Pentoxifylline should be used with caution, as a transient hypotensive effect is possible and, in isolated cases, might result in a reduction in blood flow to the heart.
- Impaired kidney function
~ Careful monitoring is required if you have kidney problem. The doctor may reduce the daily dose if you have kidney problem.
- Impaired liver function
~ In severely impaired liver function, the dosage may need to be reduced.

- Taking other medicines

Please inform your doctor or pharmacist if you are using or have recently used any other medicines. This includes medicines that you buy without prescription and herbal medicines. This is because CERATOR can affect the way some medicines work. Also some other medicines can affect the way CERATOR works.

In particular, tell your doctor or pharmacist if you are using any of the following medicines:

- Blood pressure-lowering agents
- Ketorolac
- Theophylline

How to use CERATOR

- How much to use

Dosage is generally based on the following guidelines and is determined by your doctor in accordance with individual requirements:

Usual Dose

1 tablet 2 or 3 times daily.

Swallowed whole with sufficient amount of liquid (approximately ½ glass).

For patients with kidney problem

It may be necessary to reduce the dose to 2 or 1 tablet daily. The precise reduction implemented will vary depending on how your body tolerates the medicine.

For patients with liver problem

A dose reduction, guided by individual tolerance is necessary if you have severely impaired liver function.

For patients with blood pressure problem

Treatment must be started with low dose in low blood pressure patients or patients whose circulation is unstable as well as in patients who would be at particular risk from a reduction in blood pressure (e.g. patients with heart and blood circulatory problem or narrowing of blood vessels supplying the brain); in such cases, the dose must be increased gradually.

As with any medicine, if you notice any undesirable effect, discontinue using and consult your doctor.

Follow carefully all directions given to you by your doctor and pharmacist. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

CERATOR may be taken during or shortly after a meal.

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking CERATOR for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what should you do if you forget to use it.

If you miss a dose, give the next dose as soon as you remember, provided that you do not give more than the recommended dose in 24 hours. If it is almost time for your next dose, do not take the dose that you missed.

Do not take a double dose to make up for the missed one.

- If you use too much (Overdose)

Taking too many tablets at once may make you unwell. The most likely signs of a possible overdose include flushing, loss of consciousness, "coffee-ground" -like vomit, absent reflexes, tonic-clonic convulsions (convulsion in which the muscles

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alternately contract and relax).

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else have accidentally taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

- ✓ Take your medicine exactly as your doctor has prescribed.
- ✓ Inform all the doctors, dentists and pharmacists treating you that you are taking CERATOR
- ✓ 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 medicine without consulting your doctor.
- ⊗ Do not give CERATOR to anyone else, even if they have the same symptoms or condition as you.
- ⊗ Activities requiring mental alertness: Do not drive a car or operate a potentially dangerous tools or machines that require mental alertness. This is because you may feel dizzy while taking this medicine.

- Things to be careful of

If the tablets make you feel sick, dizzy, or give you a headache, do not drive or use machines and contact your doctor immediately

Side effects

As with all drugs, CERATOR is likely to have undesirable effects, although not everybody gets them.

- Gastrointestinal side-effects: nausea, vomiting, diarrhea
- Headache, dizziness, agitation and sleep disorders
- Flushing, occasionally tachycardia (fast heartbeat) and rarely angina pectoris (constricting chest pain) and hypotension, particularly if using high doses of Pentoxifylline.
- Hypersensitivity reactions: pruritus, rash, urticaria (hives), anaphylactic or anaphylactoid (serious and rapid allergic reactions).
- Bleeding (e.g. skin, mucosa)
- Thrombocytopenia (low platelet count)

If any of the side effects happens, or if you notice any undesirable effects which have not been mentioned here, discontinue using this medication and consult your doctor / pharmacist or go to the nearest hospital immediately.

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 portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of CERATOR

- Storage

Keep medicine out of reach of children. Store at temperature of not more than 30°C

- Disposal

Medicine 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

White, oval, biconvex, film coated tablet with engraved CR-400 on one side and scored on the other

Ingredients

Active ingredient: Pentoxifylline

Inactive ingredients:

Ammonio methacrylate copolymer type A (Eudragit RL 100), Ammonio methacrylate copolymer type B (Eudragit RS 100), Crospovidone (Kollidon SR), Hydroxypropyl methylcellulose 2208 (Methocel K 15 M), Povidone K 90, Isopropyl alcohol, Acetone, Talc, Magnesium stearate, Hydroxypropyl methylcellulose 2910 (Methocel E 15 LV), Titanium dioxide, Polyethylene glycol 6000, Purified water, Simethicone emulsion 30%, Polyethylene glycol 6000

MAL. NO: MAL10120016A

Manufacturer

UNISON LABORATORIES CO., LTD.
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Product Registration Holder

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