

Cresar

Telmisartan Tablets (40mg, 80mg)

Consumer Medication Information Leaflet (RiMUP)

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What Cresar is used for

Cresar is used to treat essential hypertension (high blood pressure). 'Essential' means that the high blood pressure is not caused by any other condition.

High blood pressure, if not treated, can damage blood vessels in several organs, which could lead sometimes to heart attack, heart or kidney failure, stroke, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus it is important to regularly measure blood pressure to verify if it is within the normal range.

Cresar is also used to reduce cardiovascular events (i.e. heart attack or stroke) in patients who are at risk because they have a reduced or blocked blood supply to the heart or legs, or have had a stroke or have high risk diabetes. Your doctor can tell you if you are at high risk for such events.

How Cresar works

Cresar belongs to a class of medicines known as angiotensin II receptor antagonists. Angiotensin II is a substance produced in your body which causes your blood vessels to narrow, thus increasing your blood pressure. Cresar blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

Before you take Cresar

When you must not take it

- if you are allergic (hypersensitive) to telmisartan or any other ingredients included in Cresar (see *Product Description* for a list of other ingredients).
- if you are more than 3 months pregnant. (It is also better to avoid Cresar in early pregnancy – see *Pregnancy and breast-feeding*)
- if you have severe liver problems such as cholestasis or biliary obstruction (problems with drainage of the bile from the liver and gall bladder) or any other severe liver disease.

If any of the above applies to you, tell your doctor or pharmacist before taking Cresar.

Before you start to take it

Please tell your doctor if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Kidney disease or kidney transplant.
- Renal artery stenosis (narrowing of the renal vessels to one or both kidneys).
- Liver disease.
- Heart trouble.
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
- Low blood pressure (hypotension), likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy ('water tablets'), low-salt diet, diarrhoea, or vomiting.
- Elevated potassium levels in your blood.
- Diabetes.

You must tell your doctor if you think you are (or might become) pregnant. Cresar is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see *Pregnancy and breast-feeding*).

In case of surgery or anaesthesia, you should tell your doctor that you are taking Cresar.

The use of Cresar in children and adolescents up to the age of 18 years is not recommended.

As with all other angiotensin antagonists, Cresar may be less effective in lowering the blood pressure in black patients.

Children

The use of Cresar in children and adolescents up to the age of 18 years is not recommended.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Your doctor may need to change the dose of these other medicines or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with Cresar:

- Lithium containing medicines to treat some types of depression.
- Medicines that may increase blood potassium levels such as salt substitutes containing potassium, potassium-sparing diuretics (certain 'water tablets'), ACE inhibitors, angiotensin II receptor antagonists, NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen), heparin, immunosuppressives (e.g.

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cyclosporin or tacrolimus), and the antibiotic trimethoprim.

- Diuretics ('water tablets'), especially if taken in high doses together with Cresar, may lead to excessive loss of body water and low blood pressure (hypotension).

As with other blood pressure lowering medicines, the effect of Cresar may be reduced when you take NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids.

Cresar may increase the blood pressure lowering effect of other medicines used to treat high blood pressure.

How to use Cresar

How much to take

Always take Cresar exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose of Cresar is one tablet a day. Try to take the tablet at the same time each day.

You can take Cresar with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. If you have the impression that the effect of Cresar is too strong or too weak, talk to your doctor or pharmacist.

When to take it

For treatment of high blood pressure, the usual dose of Cresar for most patients is one 40 mg tablet once a day to control blood pressure over the 24 hour period. However, sometimes your doctor may recommend a lower dose of 20 mg or a higher dose of 80 mg. Alternatively, Cresar may be used in combination with diuretics ('water tablets') such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with Cresar.

For reduction of cardiovascular events, the usual dose of telmisartan is one 80 mg tablet once a day. At the beginning of the preventive therapy with Telmisartan 80 mg, blood pressure should be frequently monitored.

If your liver is not working properly, the usual dose should not exceed 40 mg once daily.

How long to take it

It is important that you take Cresar every day until your doctor tells you otherwise

If you forget to take it

If you forget to take a dose, do not worry. Take it as soon as you remember then carry on as before. If you do not take your tablet on one day, take your normal dose on the next day. Do not take a double dose to make up for forgotten individual doses.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you take too much (overdose)

If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately.

While you are using Cresar

Things you must do

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Cresar before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Cresar.

Cresar is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Cresar is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely

Things you must not do

Do not:

- Stop taking the medicine unless advised by your doctor.
- Take any new medicines without consulting your doctor.
- Give Telmisartan tablet to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines

No information is available on the effect of Cresar on the ability to drive or operate machinery.

Some people feel dizzy or tired when they are treated for high blood pressure. If you feel dizzy or tired, do not drive or operate machinery.

Side effects

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

The following side effects may happen with this medicine.

Common side effects may include:

Low blood pressure (hypotension) in users treated for reduction of cardiovascular events.

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Uncommon side effects may include:

- Urinary tract infections
- upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold)
- deficiency in red blood cells (anaemia)
- high potassium levels
- difficulty falling asleep
- feeling sad (depression)
- fainting (syncope)
- feeling of spinning (vertigo)
- slow heart rate (bradycardia)
- low blood pressure (hypotension) in users treated for high blood pressure
- dizziness on standing up (orthostatic hypotension)
- shortness of breath
- abdominal pain
- diarrhoea
- discomfort in the abdomen
- bloating
- vomiting
- itching
- increased sweating
- drug rash
- back pain
- muscle cramps
- muscle pain (myalgia)
- kidney impairment including acute kidney failure
- pain in the chest
- feeling of weakness
- increased level of creatinine in the blood.

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.

Reporting of side effects

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Consumers -> Reporting -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Cresar

Storage

Store below 30°C.

Keep out of the reach and sight of children.

Do not use Cresar after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

You should store your medicine in the original package in order to protect the tablets 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 **Description**

Cresar 40 (Telmisartan Tablets 40mg): White to off white, capsule shaped tablets debossed with "H" on one side and plain on other side.

Cresar 80 (Telmisartan Tablets 80mg): White to off white, oval shaped tablets debossed with "D" on one side and plain on other side.

Pack size: A carton containing blister pack of 3 X 10 tablets.

Ingredients

Active ingredient: Telmisartan

Inactive ingredients: Meglumine, sodium hydroxide, povidone, (Kollidon 30), mannitol, magnesium stearate, water purified.

MAL number

MALXXXXXXXX

Manufacturer

Jubilant Generics Limited,
Village Sikandarpur Bhainswal,
Roorkee- Dehradun Highway,
Bhagwanpur, Roorkee,
Distt-Haridwar,
Uttarakhand- 247 661 India.

Product Registration Holder

CIPLA MALAYSIA SDN BHD
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