

CASLOT TABLETS

Carvedilol Tablets (6.25 mg, 12.5 mg and 25.0 mg)

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What Caslot Tablets are used for

Caslot Tablets contain a medicine called carvedilol. This belongs to a group of medicines called 'beta-blockers'.

Caslot Tablets are used to treat the following:

- Chronic heart failure
- High blood pressure (hypertension)
- Angina (chest pain or discomfort that happens when your heart is not getting enough oxygen).

How Caslot Tablets work

Caslot Tablets work by making your blood vessels relax and widen.

- This helps to lower your blood pressure
- If you have chronic heart failure, this makes it easier for your heart to pump blood around your body
- If you have angina, this will help stop the chest pain.

Your doctor may give you other medicines as well as **Caslot Tablets** to help treat your condition.

Before you use Caslot Tablets

When you must not use it

Do not take Caslot Tablets if:

- You are allergic (hypersensitive) to carvedilol or any of the other ingredients of **Caslot Tablets** (listed in **Product Description**).
- You have ever had wheezing due to asthma or other lung diseases.
- You have severe fluid retention (swelling of your hands, ankles and feet) which is being treated by

medicines given into one of your veins (intravenously).

- You have problems with your liver.
- You have problems with your heart (for example 'heart block' or slow heart beat). **Caslot Tablets** is not suitable for some people with certain types of heart problem.
- You have very low blood pressure.

If you are not sure whether you should start taking this medicine talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- Problems with your kidney
- You have diabetes
- You wear contact lenses
- You have heart problems, slow heart beat
- You have problems with your blood vessels (peripheral vascular disease)
- You have ever had problems with your thyroid
- You have ever had a serious allergic reaction (for example, sudden swelling, causing difficulty breathing or swallowing, swelling of the hands, feet and ankles or a severe rash)
- You have an allergy and are having treatment to desensitise you.
- You have problems with the blood circulation in your fingers and toes ('Raynaud's phenomenon')
- You have had a skin disorder called 'psoriasis', after taking beta-blocker medicines
- You have a type of angina called 'Prinzmetal's variant angina'
- You have breathing problems such as asthma, bronchitis
- You have a rare tumour of adrenal glands ('phaeochromocytoma'). It results in the release of too much of chemicals like epinephrine and norepinephrine that control heart rate, metabolism, and blood pressure
- You plan to have surgery. Tell the doctor that you are taking **Caslot Tablets**. This is because some

anaesthetics can lower your blood pressure, and it may become too low.

- You are scheduled for cataract surgery and have taken or are currently taking **Caslot Tablets**. This may cause a disease called Intraoperative floppy iris syndrome. This is characterized by poor dilation of the pupil, both pre-operatively and intraoperatively, Iris billowing and floppiness, progressive constriction of the pupil (miosis) during surgery.

If you have not told your doctor about any of the above, tell them before you start taking Caslot Tablets.

Pregnancy and Lactation

Pregnancy

Tell your doctor if you are pregnant or plan to become pregnant.

It is not known whether **Caslot Tablets** is harmful to an unborn baby when taken by a pregnant woman. Your doctor will discuss the risks and benefits of using **Caslot Tablets** during your pregnancy. Do not take **Caslot Tablets**, unless your doctor has told you to.

Lactation

Do not take this medicine if you are breastfeeding. Do not take **Caslot Tablets**, unless your doctor has told you to.

Important information about some of the ingredients:

This medicine contains lactose and sucrose, which are types of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

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

- Other medicines for your heart or blood pressure, including water tablets (diuretics), 'calcium channel blockers' (for example diltiazem or verapamil), digoxin and amiodarone
- Catecholamine-depleting agents for example reserpine and Monoamine oxidase inhibitors (used to treat depression)
- Fluoxetine (used to treat depression)
- Medicines for diabetes, such as insulin or orally active antidiabetic medicines
- Clonidine (used to treat high blood pressure, migraine and flushing in the menopause)
- Rifampicin (used to treat infections)
- Cyclosporin (used after an organ transplant)
- Non-steroidal anti-inflammatory drugs, for example aspirin, indomethacin and ibuprofen
- Beta-agonist bronchodilators (used to treat chest tightness and wheezing due to asthma or other chest conditions (for example salbutamol and terbutaline sulphate))
- Other medicines that may help lower your blood pressure
- Anaesthetic agents.

How to use Caslot Tablets

How much to use

Follow all directions given to you by your doctor or pharmacist carefully.

Chronic heart failure:

When used for heart failure, treatment with **Caslot Tablets** should be started by a specialist doctor.

- The usual starting dose is one 3.125 mg tablet twice a day for two weeks
- Your doctor will then increase the dose slowly, over several weeks, up to 25 mg twice a day
- If you weigh more than 85 kg the dose may be increased up to 50 mg twice a day
- If you have stopped taking **Caslot Tablets** for more than one week you should talk to your doctor. They will need you to go back to the starting dose again.

High blood pressure:

- The usual starting dose is 12.5 mg once a day for two days

- After two days the dose is usually 25 mg, once a day.
- If your blood pressure is not under control, your doctor may increase your dose slowly, every two weeks up to 50 mg given once a day or in two divided doses.

Angina:

- The usual starting dose is 12.5 mg twice a day for two days.
- After two days the dose is usually 25 mg, twice a day. If necessary your doctor may increase the dose at the interval of at least 2 weeks to a maximum of 100 mg daily in two divided dose.

Patients with liver problems

You should not take **Caslot Tablets** if you have liver problems.

Children

Caslot Tablets should not be given to children (under 18 years of age).

When to use it

You should take your tablets at the same time.

Swallow tablets with a glass of water. **Caslot Tablets** should be taken with food.

How long to use it

Do not stop taking this medicine without talking to your doctor. They may want you to stop taking

Caslot Tablets slowly over 1 to 2 weeks.

If you forget to use it

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you use too much (overdose)

If you think you or anyone else may have taken too much **Caslot Tablets**, immediately telephone your doctor or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

If you are not sure what to do, contact your doctor or pharmacist.

You may need urgent medical attention.

The following are some symptoms, which may or may not occur.

- low blood pressure, causing dizziness or fainting
- a very slow heart rate
- heart failure
- difficulty breathing
- vomiting
- shock
- disturbed consciousness
- Seizures.

While you are using it

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking **Caslot Tablets**. You should also tell your surgeon and anaesthetist if you are having surgery.

Tell your doctor if you become pregnant or breast feeding while taking **Caslot Tablets**.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Your doctor may examine your eyes and test your blood glucose and kidney function from time to time.

Things you must not do

Do not stop taking **Caslot Tablets** or change the dose without first checking with your doctor.

Caslot Tablets should only be stopped by gradually reducing the amount over a two-week period.

Do not give **Caslot Tablets** to anyone else even if they have the same condition as you.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how

Caslot Tablets affects you.

Caslot Tablets may affect your ability to drive a car or operate machinery when started or when the dosage is increased or in combination with alcohol.

If you wear contact lenses you may also notice a reduction in the amount of tear fluid in your eyes.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are applying Caslot Tablets.

Caslot Tablets can cause side effects, although not everybody gets them.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

If any of the following happens, tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (hypersensitivity reaction)
- Blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be Stevens-Johnson syndrome, erythema multiforme or toxic epidermal necrolysis.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

- Tiredness, headaches, being short of breath when exercising, dizziness and looking pale (anaemia)
- Bleeding or bruising more easily than normal (thrombocytopenia, purpura)
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers (leukopenia)
- Sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness,

having a fast, pounding heart beat (hypoglycaemia)

- Passing large amounts of urine, excessive thirst and having a dry mouth and skin (hyperglycaemia)

Caslot Tablets can also cause development of the signs of diabetes in people who have a very mild form of diabetes called 'latent diabetes'.

- Depression
- Fluid retention. The signs include: overall swelling of your body, swelling of parts of your body for example your hands, feet, ankles, legs and lungs and an increase in how much blood you have in your body
- Heart failure
- Heart block, decreased blood supply to heart characterised by chest pain (myocardial ischaemia)
- Problems with blood circulation in your arms and legs. The signs include cold hands and feet, whiteness, tingling and pain in your fingers and a pain in your leg which gets worse when you walk
- Kidney failure, change in frequency of passing urine
- Some women may have difficulty with bladder control when they pass water (urinary incontinence). This will normally get better when treatment is stopped
- Low blood volume causing very low blood pressure
- Stroke
- Convulsions
- Severe stabbing or throbbing pain along one or more nerves (neuralgia)
- Vomiting blood or material that looks like coffee grounds, bloody diarrhoea (gastrointestinal haemorrhage)
- Coughing, difficulty breathing, wheezing (Interstitial pneumonitis)

The above list includes serious side effects that may require medical attention.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Infections of the airway (bronchitis), lung (pneumonia), nose and throat (upper respiratory tract). The signs include wheezing, shortness of breath, chest tightness and sore throat.

- Weight gain or weight loss
- Depressed mood
- Sleeping problems
- Dizziness, headache, fainting, fatigue
- Pain
- Lightheadedness, muscular weakness, and feeling faint (presyncope)
- Pins and needles
- Visual impairment, dry eyes, decreased lacrimation
- Chest pain (angina)
- Decreased blood pressure, dizziness on standing up, especially when getting up from a sitting or lying position
- Difficulty in breathing (dyspnoea) and other breathing problems
- A stuffy nose, wheezing and flu-like symptoms
- Feeling sick (nausea), being sick (vomiting), diarrhoea, indigestion, stomach pain, constipation
- Dry mouth
- Problems with your skin, including skin rashes which may cover a lot of your body, a lumpy rash (hives), feeling itchy and dry skin patches
- Loss of hair
- Increased sweating
- Pain in legs and hands
- Being unable to get an erection (erectile dysfunction), decreased sexual drive
- Joint pain, joint inflammation
- Cough
- Fever
- Palpitations
- High blood pressure
- Decreased feeling or sensitivity, especially in the skin (hypesthesia)
- Spinning sensation
- Black colour stool
- Breath odour, gums that appear bright red or red-purple, gums that bleed easily (blood on toothbrush even with gentle brushing of the teeth), loose teeth, swollen gums (periodonitis)
- Muscle cramps, Low muscle strength
- Slow or rapid heart beat
- Slow body movement (hypokinesia)
- Nervousness, impaired concentration, abnormal thinking
- Terrifying dreams, emotional lability
- Ringing in ear, decreased hearing
- Dizziness, light-headedness, numbness of the hands and feet

(condition marked by low levels of carbon dioxide known as respiratory alkalosis)

- Increase urine frequency
- Migraine
- Weakness of voluntary movement
- Disease with painful, swollen joints caused by uric acid crystals (gout)
- Loss of memory

Laboratory abnormalities

- Low number of blood cells (red & white blood cells and platelets)
- Abnormal type of white blood cells
- Increase blood cholesterol and triglycerides level and decreased HDL (types of fat)
- High or low level of blood glucose level
- Increase in ALT, AST, GGT and alkaline phosphatase levels (indicate problem with your liver)
- Increased in blood urea nitrogen and non protein nitrogen
- Increase level of uric acid in blood
- Low level of nitrogen in blood
- Increase or decrease level of potassium in blood
- Increased in blood creatinine level
- Presence of glucose in urine (indicate high level of glucose in blood)
- Decreased in prothrombin (indicator of blood clotting time)
- Presence of protein (albumin) in urine
- Blood in urine
- Presence of excess bilirubin in the blood

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 Caslot Tablets

Storage

Store below 30°C, protected from moisture

Disposal

Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal.

Product description

What Caslot Tablets look like

Caslot Tablets 6.25 mg :

Yellow coloured, circular, biconvex, uncoated mottled tablets with a score-line on one side and plain on the other.

Caslot Tablets 12.5 mg :

Peach coloured, circular, biconvex, uncoated mottled tablets with a score-line on one side and plain on the other.

Caslot Tablets 25 mg :

White to off-white, circular, biconvex, uncoated mottled tablets with a score-line on one side and plain on the other.

Ingredients

Active ingredient:

Carvedilol 6.25 mg, 12.5 mg and 25 mg

Inactive ingredients:

Lactose Monohydrate, Crospovidone, Colloidal Silicon Dioxide, Povidone K 30, Sucrose, Purified Water, Magnesium Stearate (veg), Ferric Oxide (Yellow), Ferric Oxide (Red)

MAL NO:

Caslot Tablets 6.25 mg :

MAL06021195A

Caslot Tablets 12.5 mg :

MAL06021196A

Caslot Tablets 25.0 mg :

MAL05090004A

Manufacturer and Product Registration Holder

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