

Package leaflet: Information for the user

Amlodipine Clonmel 5mg Tablets Amlodipine Clonmel 10mg Tablets

Amlodipine (as besilate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Amlodipine Clonmel is and what it is used for
2. What you need to know before you take Amlodipine Clonmel
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1. What Amlodipine Clonmel is and what it is used for

Amlodipine Clonmel contains the active substance amlodipine which belongs to a group of medicines called calcium antagonists.

Amlodipine Clonmel is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina, a rare form of which is Prinzmetal's or variant angina.

In patients with high blood pressure this medicine works by relaxing blood vessels, so that blood passes through them more easily. In patients with angina Amlodipine Clonmel works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. This medicine does not provide immediate relief of chest pain from angina.

2. What you need to know before you take Amlodipine Clonmel

DO NOT take Amlodipine Clonmel

- If you are allergic to amlodipine or any of the other ingredients of this medicine (listed in section 6) or to any other calcium antagonists. This may be itching, reddening of the skin or difficulty in breathing.
- If you have severe low blood pressure (hypotension).
- If you have narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- If you suffer from heart failure after a heart attack.

Warnings and precautions

Talk to your doctor or pharmacist before taking Amlodipine Clonmel.

You should inform your doctor if you have or have had any of the following conditions:

- Recent heart attack
- Heart failure
- Severe increase in blood pressure (Hypertensive crisis)
- Liver disease
- You are elderly and your dose needs to be increased.

Children and adolescents

Amlodipine has not been studied in children under the age of 6 years. Amlodipine Clonmel should only be used for hypertension in children and adolescents from 6 years to 17 years of age (see section 3). For more information, talk to your doctor.

Other medicines and Amlodipine Clonmel

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

Amlodipine Clonmel may affect or be affected by other medicines, such as:

- ketoconazole, itraconazole (anti-fungal medicines)
- ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV)
- rifampicin, erythromycin, clarithromycin (antibiotics - for infections caused by bacteria)
- hypericum perforatum (St. John's Wort)
- verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- simvastatin (used to reduce elevated cholesterol levels in the blood)
- tacrolimus (used to control your body's immune response, enabling your body to accept the transplanted organ)
- cyclosporine (an immunosuppressant)

Amlodipine Clonmel may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure.

Amlodipine Clonmel with food and drink

Grapefruit juice and grapefruit should not be consumed by people who are taking Amlodipine Clonmel. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Amlodipine Clonmel.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

The safety of amlodipine in human pregnancy has not been established.

Breast-feeding

Amlodipine has been shown to pass into breast milk in small amounts. If you are breast-feeding or about to start breast-feeding you must tell your doctor before taking Amlodipine Clonmel.

Driving and using machines

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

Amlodipine Clonmel contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Amlodipine Clonmel

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended initial dose is 5 mg Amlodipine Clonmel once daily. The dose can be increased to 10 mg Amlodipine Clonmel once daily.

The Amlodipine Clonmel 10 mg tablet can be divided into equal doses.

This medicine can be taken before or after food and drinks. You should take this medicine at the same time each day with a drink of water. Do not take Amlodipine Clonmel with grapefruit juice.

Use in children and adolescents

For children and adolescents (6–17 years old), the recommended usual starting dose is 2.5 mg a day. The maximum recommended dose is 5 mg a day.

Amlodipine 2.5 mg is not currently available and the 2.5 mg dose cannot be obtained with Amlodipine Clonmel 5 mg tablets as these tablets are not manufactured to break into two equal doses.

It is important to keep taking the tablets. Do not wait until your tablets are finished before seeing your doctor.

If you take more Amlodipine Clonmel than you should

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness. Seek immediate medical attention if you take too many Amlodipine Clonmel tablets.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

If you forget to take Amlodipine Clonmel

Do not worry. If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Amlodipine Clonmel

Your doctor will advise you how long to take your medicine. Your condition may return if you stop using your medicine before you are advised.

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

4. Possible side effects

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

Visit your doctor **immediately** if you experience any of the following severe side effects after taking this medicine.

- Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing
- Swelling of eyelids, face or lips
- Swelling of the tongue and throat which causes great difficulty breathing
- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens-Johnson syndrome, toxic epidermal necrolysis) or other allergic reactions
- Heart attack, abnormal heart beat
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell

The following very common side-effect has been reported. If this causes you problems or if it lasts for more than one week, you should contact your doctor.

Very common (may affect more than 1 in 10 people):

- Oedema (fluid retention)

Common (may affect up to 1 in 10 people):

- Headache, dizziness, sleepiness (especially at the beginning of treatment)
- Palpitations (awareness of your heart beat), flushing

- Abdominal pain, feeling sick (nausea)
- Altered bowel habits, diarrhoea, constipation, indigestion
- Tiredness, weakness
- Visual disturbances, double vision
- Muscle cramps
- Ankle swelling

Other side-effects that have been reported include the following list. If any of these get serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

Uncommon (may affect up to 1 in 100 people):

- Mood changes, anxiety, depression, sleeplessness
- Trembling, taste abnormalities, fainting
- Numbness or tingling sensation in your limbs; loss of pain sensation
- Ringing in the ears
- Low blood pressure
- Sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
- Cough
- Dry mouth, vomiting (being sick)
- Hair loss, increased sweating, itchy skin, red patches on skin, skin discolouration
- Disorder in passing urine, increased need to urinate at night, increased number of times of passing urine
- Inability to obtain an erection; discomfort or enlargement of the breasts in men
- Pain, feeling unwell
- Joint or muscle pain, back pain
- Weight increase or decrease

Rare (may affect up to 1 in 1,000 people):

- Confusion

Very rare (may affect up to 1 in 10,000 people):

- Decreased numbers of white blood cells, decrease in blood platelets which may result in unusual bruising or easy bleeding (red blood cell damage)
- Excess sugar in blood (hyperglycaemia)
- A disorder of the nerves which can cause muscular weakness, tingling or numbness
- Swelling of the gums
- Abdominal bloating (gastritis)
- Abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests
- Increased muscle tension
- Inflammation of blood vessels, often with skin rash
- Sensitivity to light
- Disorders combining rigidity, tremor, and/or movement disorders

Not known (frequency cannot be estimated from the available data):

- Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Amlodipine Clonmel

Keep this medicine out of the sight and reach of children.

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

Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Amlodipine Clonmel contains

The active substance is amlodipine (as besilate).

Amlodipine Clonmel 5 mg tablets:

- **Each tablet contains 5 mg of amlodipine (as besilate).**
- The other ingredients are: microcrystalline cellulose (E460), calcium hydrogen phosphate (E341), sodium starch glycolate, magnesium stearate (E470b).

Amlodipine Clonmel 10 mg tablets:

- **Each tablet contains 10 mg of amlodipine (as besilate).**
- The other ingredients are: microcrystalline cellulose (E460), calcium hydrogen phosphate (E341), sodium starch glycolate, magnesium stearate (E470b).

What Amlodipine Clonmel looks like and contents of the pack

Amlodipine Clonmel 5 mg tablets:

Amlodipine Clonmel 5 mg tablets are white, round tablets.

Blister packs with 7, 10, 14, 15, 20, 28, 30, 50, 56, 60, 100, 120 tablets or 7x1, 10x1, 14x1, 15x1, 20x1, 28x1, 30x1, 50x1, 56x1, 60x1, 100x1 and 120x1 tablets in perforated unit dose blisters.

Amlodipine Clonmel 10 mg tablets:

Amlodipine Clonmel 10 mg tablets are white, round tablets with a break score on one side. The tablet can be divided into equal doses.

Blister packs with 7, 10, 14, 15, 20, 28, 30, 50, 56, 60, 100, 120 tablets or 7x1, 10x1, 14x1, 15x1, 20x1, 28x1, 30x1, 50x1, 56x1, 60x1, 100x1 and 120x1 tablets in perforated unit dose blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel. Co. Tipperary, Ireland.

Manufacturer:

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

Clonmel Healthcare Ltd, Waterford Road, Clonmel. Co. Tipperary, Ireland

Specifar S.A., 1, 28 Octovriou str., Ag. Varvara, Athens 12351, Greece

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Amlodipin besilat STADA 5 mg Tabletten Amlodipin besilat STADA 10 mg Tabletten
Denmark:	Amlodistad
Germany:	Amlodipin(besilat) AL 5 mg Tabletten Amlodipin(besilat) AL 10 mg Tabletten
Spain:	Amlodipino STADA 5 mg comprimidos EFG Amlodipino STADA 10 mg comprimidos EFG
Ireland:	Amlodipine Clonmel 5 mg tablets

Portugal: Amlodipine Clonmel 10 mg tablets
Amlodipina Ciclum
Sweden: Amlodistad

This leaflet was last revised in June 2022.