Package leaflet: Information for the patient

Amlodipine Zentiva 2.5 mg Tablets
Amlodipine Zentiva 5 mg Tablets
Amlodipine Zentiva 10 mg Tablets

(Amlodipine 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 Zentiva is and what it is used for
2. What you need to know before you take Amlodipine Zentiva
3. How to take Amlodipine Zentiva
4. Possible side effects
5. How to store Amlodipine Zentiva
6. Contents of the pack and other information

1. What Amlodipine Zentiva is and what it is used for

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

Amlodipine Zentiva 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 Zentiva 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 Zentiva

Do not take Amlodipine Zentiva 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. Signs of an allergic reaction may include itching, reddening of the skin or difficulty in breathing.
- have severe low blood pressure (hypotension).
- 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).
- suffer from heart failure after a heart attack.

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

Other medicines and Amlodipine Zentiva
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Amlodipine Zentiva 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).
- tacrolimus, sirolimus, temsirolimus and everolimus (medicines used to alter the way your immune system works.)
- simvastatin (medicine used to treat high blood cholesterol level).
- ciclosporin (an immunosuppressant).

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

Amlodipine Zentiva with food and drink
Grapefruit juice and grapefruit should not be consumed by people who are taking Amlodipine Zentiva. 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 Zentiva.

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 breastfeeding or about to start breast-feeding you must tell your doctor before taking Amlodipine Zentiva.

Driving and using machines
Amlodipine Zentiva 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.

Important information about the ingredients of Amlodipine Zentiva
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take Amlodipine Zentiva

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

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

This medicine can be used 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 Zentiva 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.

If you take more Amlodipine Zentiva 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.

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

Seek immediate medical attention if you take too many Amlodipine Zentiva tablets.

If you forget to take Amlodipine Zentiva
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 Zentiva
Your doctor will advise you how long to take this medicine. Your condition may return if you stop using this medicine before you are advised to.
It is important to keep taking the tablets. Do not wait until your tablets are finished before seeing your doctor.

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 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 an 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.
- An inflamed pancreas which may cause severe abdominal and back pain accompanied by 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).

The following **common side effects** have been reported. If any of these cause you problems or if they **last for more than one week**, you should **contact your doctor**.

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 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.
- Excess sugar in blood (hyperglycaemia).
- A disorder of the nerves which can cause muscular weakness, tingling or numbness.
- Swelling and/or bleeding of the gums.
- Inflammation of the stomach (gastritis) that may include abdominal bloating.
- 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Amlodipine Zentiva

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/blister after EXP. The expiry date refers to the last day of that month.
Store below 25°C, 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 Zentiva contains
Each 2.5 mg tablet contains Amlodipine Besilate equivalent to 2.5 mg amlodipine.
Each 5 mg tablet contains Amlodipine Besilate equivalent to 5 mg amlodipine.
Each 10 mg tablet contains Amlodipine Besilate equivalent to 10 mg amlodipine.
The other ingredients are microcrystalline cellulose, sodium starch glycolate A, calcium hydrogen phosphate, magnesium stearate.

What Amlodipine Zentiva looks like and contents of the pack
Amlodipine Zentiva 2.5 mg tablets: white to off-white uncoated round biconvex tablets with diameter 5 mm.
Amlodipine Zentiva 5 mg tablets: white to almost white oblong tablets, size 9 x 4.5 mm, with a scoreline on one side, debossed with “A” and “5” marks left and right of the scoreline. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
Amlodipine Zentiva 10 mg tablets: white to almost white oblong tablets, size 12 x 6 mm, with a scoreline on one side, debossed with “A” and “10” marks left and right of the scoreline. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
Amlodipine Zentiva 2.5 mg, 5 mg and 10 mg Tablets are available in either, transparent PVC/Aluminium blisters, white PVC/PVDC/ Aluminium blisters or white PVC/Aluminium blisters.
Amlodipine Zentiva 2.5 mg is also available in transparent PVC/PVDC/Aluminium blisters.

The pack contains 28 tablets.

The Marketing Authorisation Holder is
Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, United Kingdom

The Manufacturer is
ZENTIVA k. s., U Kabelovny 130, Dolní Měcholupy 102 37 Prague 10, Czech Republic

This leaflet was last revised in November 2023

ZENTIVA

GENERAL INFO:

PM CODE:	ZV/715 67
PRODUCT NAME:	AMLODIPINE ZTV TAB GB
SAP ID / GMID:	11009970; 11010111; 11010112
AW VERSION:	V5
CREATION DATE:	21.11.2023
AW BY:	LP
SUPPLIER:	N/A

REASON FOR CHANGE:

PRG - see reason for change in Vista

TECHNICAL INFO:

FORMAT (size):	160 x 400 mm
LAETUS (pharma code):	(2434) 0011011011; L - 3, C - 0, R - 4
FONT + MIN. SIZE:	Helvetica Neue LT W1G 9 pt
MATERIAL TYPE (TS):	N/A

COLOURS: [1]

■ Black

TECH. COLOURS: [1]

■ DieCut

This line = the place a bend of a leaflet

direction of Code reading

10

2

8

8

2

10

direction of Code reading

Fiber direction

ZENTIVA **artwork check list**

Infobox check		
PM code	(acc. Vista)	OK
Product name	(acc. Vista)	OK
SAP ID / GMID	(acc. Vista)	OK
Colors	(add only used colors)	OK

Technical check		
Keyline	(acc. pack size/strength/dosage form)	OK
Inner safezones	(acc. keyline)	OK
Leatus code:	position and orientation	OK
	value of code	OK

Design check		
Corresponds to:	leaflet design manual	OK
	registered mockup	OK
PM code placed on artwork	(acc. Vista)	OK
Color separations	(are colors used properly?)	OK
Logo placement	(check if proper logo is used)	OK

Legislation check		
Font size	(minimum font size is 8.5 pt - Helvetica)	OK
Line spacing	(minimum line spacing is 8.5 pt)	OK
Text according to:	QRD (text used acc. Vista)	N/A
	Annotated PDF (acc. Vista)	OK

New version check		V5
Update infobox	(version and other data if needed)	OK
Applied corrections	(check if only requested corrections have been applied)	OK