

## What is in this leaflet

1. What TWYNSTA is used for
2. How TWYNSTA works
3. Before you use TWYNSTA
4. How to use TWYNSTA
5. While you are using it
6. Side effects
7. Storage and Disposal of TWYNSTA
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

## What TWYNSTA is used for

TWYNSTA is a prescription medicine that contains telmisartan and amlodipine. TWYNSTA tablets may be used to treat high blood pressure (hypertension):

- when one of these medicines (or a similar one) is not enough to lower your high blood pressure
- as the first medicine to lower your high blood pressure if your doctor decides you are likely to need more than one medicine

It is not known if TWYNSTA is safe and effective in children.

## How TWYNSTA works

TWYNSTA tablets contain two active substances called telmisartan and amlodipine. Both of these substances help to control your high blood pressure: - Telmisartan belongs to a group of substances called “angiotensin-II receptor antagonists”.

Angiotensin II is a substance produced in the body which causes blood vessels to narrow, thus increasing blood pressure. Telmisartan works by blocking the effect of angiotensin II.

- Amlodipine belongs to a group of substances called “calcium channel blockers”. Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.

This means that both of these active substances work together to help stop your blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.

## Before you use TWYNSTA

### - When you must not use it

- if you are allergic to telmisartan or amlodipine or any of the other ingredients of this medicine (listed in *section 8 Product Description – Ingredient*).
- if you are allergic to other medicines of the dihydropyridine type (one type of calcium channel blocker).
- if you are more than 3 months pregnant. (It is also better to avoid TWYNSTA in early pregnancy – see Warnings and precautions and Pregnancy section.)
- if you have severe liver problems or biliary obstruction (problems with drainage of the bile from the liver and gall bladder).
- if you suffer from severe low blood pressure (including shock).
- if you suffer from low heart output because of a serious heart problem.

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

### Pregnancy and lactation

#### Pregnancy

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

### - Before you start to use it

Before you take TWYNSTA tablets, tell your doctor if you:

- have liver problems
- have kidney problems
- have heart problems
- have any other medical conditions
- are pregnant or are planning to become pregnant.
- are breast-feeding or plan to breast-feed.
- have diabetes mellitus or impaired kidney function and you are treated with aliskiren.

### - Taking other medicines

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

For patients with diabetes, if you are taking TWYNSTA you should not take aliskiren.

TWYNSTA may affect the way other medicines work, and other medicines may affect how TWYNSTA works. Especially tell your doctor if you take:

- aliskiren
- digoxin
- lithium
- medicines used to treat pain and arthritis, called non-steroidal anti-inflammatory drugs (NSAIDs), including COX-2 inhibitors
- ramipril or other medicines that may be used to treat high blood pressure or a heart problem
- simvastatin
- water pills (diuretics)

Know the medicines you take. Keep a list of them and show it to your doctor or pharmacist when you get a new medicine.

## How to use TWYNSTA

### - How much to use

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

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

Remove your TWYNSTA tablet from the blister only directly prior to intake.

If your liver is not working properly, the usual dose should not exceed one 40 mg/5 mg tablet or one 40 mg/10 mg tablet per day.

- When to use it

Use as directed by your doctor or pharmacist.

You can take TWYNSTA with or without food. The tablets should be swallowed with some water or other non-alcoholic drink.

Grapefruit juice and grapefruit should not be consumed when you take TWYNSTA. This is because grapefruit and grapefruit juice may lead to increased blood levels of the active ingredient amlodipine in some patients and may increase the blood pressure lowering effect of TWYNSTA.

- How long to use it

It is important that you take TWYNSTA every day until your doctor tells you otherwise. If you have the impression that the effect of TWYNSTA is too strong or too weak, talk to your doctor or pharmacist. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you forget to use it

If you forget to take a dose, take it as soon as you remember and 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 use too much (overdose)

If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately. You might experience low blood pressure and rapid heart beat. Slow heart beat, dizziness, reduced kidney function including kidney failure, marked and prolonged low blood pressure including shock and death have also been reported.

**While you are using it**

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking TWYNSTA.

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 medicines without consulting your doctor.

Do not give TWYNSTA to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

**Driving and using machines**

Some people may experience side effects such as fainting, sleepiness, dizziness or a feeling of spinning (vertigo) when they are treated for high blood pressure. If you experience these side effects, do not drive or use machines.

**Side effects**

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

The most common side effects of TWYNSTA tablets include:

- swelling in your hands, ankles, or feet
- dizziness

These are not all the possible side effects of TWYNSTA tablets. Tell your doctor if you have any side effect that bothers you or that does not go away.

Call your doctor for medical advice about 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: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

**Storage and Disposal of TWYNSTA**

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

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

Twynsta 40/5mg - blue and white oval shaped two layer tablets engraved with the product code A1 and the company logo on the other side.

Twynsta 40/10mg - blue and white oval shaped two layer tablets engraved with the product code A2 and the company logo on the other side.

Twynsta 80/5mg - blue and white oval shaped two layer tablets engraved with the product code A3 and the company logo on the other side.

Twynsta 80/10mg - blue and white oval shaped two layer tablets engraved with the product code A4 and the company logo on the other side.

- Ingredients

- Active ingredient(s)

Twynsta 40/5mg - Each tablet contains 40 mg telmisartan and 5 mg amlodipine (as besilate).

Twynsta 40/10mg - Each tablet contains 40 mg telmisartan and 10 mg amlodipine (as besilate).

Twynsta 80/5mg - Each tablet contains 80 mg telmisartan and 5 mg amlodipine (as besilate).

Twynsta 80/10mg - Each tablet contains 80 mg telmisartan and 10 mg amlodipine (as besilate).

- Inactive ingredients

Colloidal anhydrous silica, brilliant blue FCF (E133), ferric oxide black (E172), ferric oxide yellow (E172), magnesium stearate, maize starch, meglumine, microcrystalline cellulose, povidone K25, pregelatinized starch, sodium hydroxide, sorbitol (E420).

- MAL number(s):

Twynsta 40/5mg - MAL20112135AC

Twynsta 40/10mg - MAL20112136AC

Twynsta 80/5mg - MAL20112137AC

Twynsta 80/10mg - MAL20112138AC

**Manufacturer**

Manufactured by:  
Cipla Limited  
Verna Industrial Estate,  
Goa-403 722, India.  
for Boehringer Ingelheim International  
GmbH  
Ingelheim am Rhein, Germany

**Product Registration Holder**

Boehringer Ingelheim (Malaysia) Sdn.  
Bhd.  
Suite 15-5 Level 15,  
Wisma UOA Damansara II,  
No. 6 Jalan Changkat Semantan,  
Damansara Heights,  
50490 Kuala Lumpur.

**Date of revision**

29/01/2014