Package leaflet: Information for the user

Twynsta®
80 mg/5 mg tablets

Telmisartan/Amlodipine

Boehringer Ingelheim

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

1. What Twynsta is and what it is used for

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.

Twynsta is used to treat high blood pressure
- in adult patients whose blood pressure is not controlled enough with amlodipine alone.
- in adult patients who already receive telmisartan and amlodipine from separate tablets and who wish to take instead the same doses in one tablet for convenience.

High blood pressure, if not treated, can damage blood vessels in several organs, which puts patients at risk of serious events such as 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.

2. What you need to know before you take Twynsta

Do not take Twynsta

- if you are allergic to telmisartan or amlodipine or any of the other ingredients of this medicine (listed in section 6).
- 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 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 low heart output because of a serious heart problem.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

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

Warnings and precautions

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

- Kidney disease or kidney transplant.
- Narrowing of the blood vessels to one or both kidneys (renal artery stenosis).
- Liver disease.
- Heart trouble.
- Raised aldosterone levels (which lead to 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.
- Narrowing of the aorta (aortic stenosis).
- Heart-associated chest pain also at rest or with minimal effort (unstable angina pectoris).
- A heart attack within the last four weeks.

Talk to your doctor before taking Twynsta:
- if you are taking any of the following medicines used to treat high blood pressure:
  - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
  - aliskiren.
  Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals. See also "Do not take Twynsta".
- if you are taking digoxin, a medicine used for the treatment of heart failure.

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

Children and adolescents

Twynsta is not recommended in children and adolescents up to the age of 18 years.

Other medicines and Twynsta

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

- 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').
- Angiotensin II receptor antagonists.
- ACE-inhibitors or aliskiren (see also information under the headings "Do not take Twynsta" and "Warnings and precautions").
- NSAIDs (non steroidal anti-inflammatory medicines, e.g. acetylsalicylic acid or ibuprofen), heparin, immunosuppressives (e.g. cyclosporin or tacrolimus), and the antibiotic trimethoprim.
- Rifampicin, St. John's wort.
- Medicines used for HIV/AIDS (e.g. ritonavir) or for treatment of fungal infections (e.g. ketoconazole).
- Erythromycin (antibiotic).
- Diltiazem (cardiac medicine).
- Simvastatin to treat elevated levels of cholesterol.
- Digoxin.

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

Twynsta may increase the blood pressure lowering effect of other medicines used to treat high blood pressure or of medicines with blood pressure lowering potential (e.g. baclofen, amifostine, neuroleptics or antidepressants).

Twynsta with food and drink

Low blood pressure may be aggravated by alcohol. You may notice this as dizziness when standing up.

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.

Pregnancy and breast-feeding

Pregnancy
You must tell your doctor if you think you might be pregnant or are planning to have a baby. 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.

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.

Twynsta contains sorbitol

If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine.

3. How to take Twynsta

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.

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

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.

If you take more Twynsta than you should

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.

If you forget to take Twynsta

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 stop taking Twynsta

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.

4. Possible side effects

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

Some side effects can be serious and need immediate medical attention:

You should see your doctor immediately if you experience any of the following symptoms:

Sepsis (often called "blood poisoning", is a severe infection of the whole body with high fever and the feeling of being severely ill), rapid swelling of the skin and mucosa (angioedema); these side effects are rare (may affect up to 1 in 1,000 people) but are extremely serious and patients should stop taking the medicine and see their doctor immediately. If these effects are not treated they could be fatal. Increased incidence of sepsis has been observed with telmisartan only, however can not be ruled out for Twynsta.

Common side effects (may affect up to 1 in 10 people):
Dizziness, ankle swelling (oedema).

Uncommon side effects (may affect up to 1 in 100 people):
Sleepiness, migraine, headache, tingling or numbness of the hands or feet, feeling of spinning (vertigo), slow heart rate, palpitations (awareness of your heart beat), low blood pressure (hypotension), dizziness on standing up (orthostatic hypotension), flushing, cough, stomach ache (abdominal pain), diarrhoea, feeling sick (nausea), itching, joint pain, muscle cramps, muscle pain, inability to obtain an erection, weakness, chest pain, tiredness, swelling (oedema), increased levels of hepatic enzymes.

Rare side effects (may affect up to 1 in 1,000 people):
Urinary bladder infection, feeling sad (depression), feeling anxious, sleeplessness, fainting, nerve damage in the hands or feet, reduced sense of touch, taste abnormalities, trembling, vomiting, enlarged gums, discomfort in the abdomen, dry mouth, eczema (a skin disorder), redness of skin, rash, back pain, leg pain, urge to urinate during the night, feeling unwell (malaise), increased levels of uric acid in the blood.

Very rare side effect (may affect up to 1 in 10,000 people):
Progressive scarring of lung tissue (interstitial lung disease [mainly pneumonia of the interstitium and pneumonia with excess eosinophils])

The following side effects have been observed with the components telmisartan or amlodipine and may occur also with Twynsta:

Telmisartan
In patients taking telmisartan alone the following additional side effects have been reported:

Uncommon side effects (may affect up to 1 in 100 people):
Urinary tract infections, upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold), deficiency in red blood cells (anaemia), high potassium levels in the blood, shortness of breath, bloating, increased sweating, kidney damage including sudden inability of the kidneys to work, increased levels of creatinine.

Rare side effects (may affect up to 1 in 1,000 people):
Increase in certain white blood cells (eosinophilia), low platelet count (thrombocytopenia), allergic reaction (e.g. rash, itching, difficulty of breathing, wheezing, swelling of the face or low blood pressure), low blood sugar levels (in diabetic patients), impaired vision, fast heart beat, upset stomach, abnormal liver function, hives (urticaria), medicine rash, inflammation of the tendons, flu-like illness (for example muscle pain, feeling generally unwell), decreased haemoglobin (a blood protein), increased levels of creatinine phosphokinase in the blood.

Most cases of abnormal liver function and liver disorder from post-marketing experience with telmisartan occurred in Japanese patients. Japanese patients are more likely to experience this side effect.

Amlodipine
In patients taking amlodipine alone the following additional side effects have been reported:

Uncommon side effects (may affect up to 1 in 100 people):
Mood changes, impaired vision, ringing in the ears, shortness of breath, sneezing/running nose, change of bowel habit, hair loss, unusual bruising and bleeding (red blood cell damage), skin discolouration, increased sweating, difficulty passing urine, increased need to pass urine especially at night, enlarging of male breasts, pain, weight increased, weight decreased.

Rare side effects (may affect up to 1 in 1,000 people):
Confusion.

Very rare side effects (may affect up to 1 in 10,000 people):
Reduced number of white blood cells (leucopenia), low platelet count (thrombocytopenia), allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure), excess sugar in blood, uncontrollable twitching or jerking movements, heart attack, irregular heart beat, inflammation of the blood vessels, inflamed pancreas, inflammation of the stomach lining (gastritis), inflammation of the liver, yellowing of the skin (jaundice), increased levels of hepatic enzymes with jaundice, rapid swelling of skin and mucosa (angioedema), severe skin reactions, hives (urticaria), severe allergic reactions with blistering eruptions of the skin and mucous membranes (exfoliative dermatitis, Stevens-Johnson-Syndrome), increased sensitivity of the skin to sun.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme Website:
www.mhra.gov.uk/yellowcard

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL – Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
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Malta
ADR Reporting
The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D'Argens
GŻR-1368 Gżira
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store Twynsta

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 and blister after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from light and moisture. Remove your Twynsta tablet from the blister only directly prior to intake.

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 Twynsta contains

- The active substances are telmisartan and amlodipine.
  Each tablet contains 80 mg telmisartan and 5 mg amlodipine (as amlodipine besylate).

- The other ingredients are 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 prepared from maize starch, sodium hydroxide, sorbitol (E420).

What Twynsta looks like and contents of the pack

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

Twynsta is available in a folding box containing 14, 28, 56, 98 tablets in aluminium/aluminium blisters or containing 30 x 1, 90 x 1, 360 (4 x 90 x 1) tablets in aluminium/aluminium perforated unit dose blisters.

Not all pack sizes may be marketed.

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/.