APPROVED PATIENT INFORMATION LEAFLET - TWYNSTA

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Twynsta® 40/5 mg
Twynsta® 40/10 mg
Twynsta® 80/5 mg
Twynsta® 80/10 mg

abcd

tablets

Telmisartan/Amlodipine

Read all of this leaflet carefully before you start taking TWYNSTA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your health care provider.
- TWYNSTA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT TWYNSTA CONTAINS

TWYNSTA tablets contain two active substances called telmisartan and amlodipine.
TWYNSTA 40/5 mg tablets: Each tablet contains 40 mg telmisartan and 5 mg amlodipine base (as besylate salt).

TWYNSTA 40/10 mg tablets: Each tablet contains 40 mg telmisartan and 10 mg amlodipine base (as besylate salt).

TWYNSTA 80/5 mg tablets: Each tablet contains 80 mg telmisartan and 5 mg amlodipine base (as besylate salt).

TWYNSTA 80/10 mg tablets: Each tablet contains 80 mg telmisartan and 10 mg amlodipine base (as besylate salt).

The other ingredients are colloidal anhydrous silica, FD&C blue No. 1 aluminium lake, ferric oxide black, ferric oxide yellow, magnesium stearate, maize starch, meglumine, microcrystalline cellulose, povidone K25, pregelatinised starch, sodium hydroxide, sorbitol.
Contains sugar (sorbitol). TWYNSTA 40/5 mg and 40/10 mg tablets contain 168,64 mg sorbitol and TWYNSTA 80/5 mg and 80/10 mg tablets contain 337,28 mg sorbitol in each tablet.

2. WHAT TWYNSTA IS USED FOR

TWYNSTA is used to treat high blood pressure (also known as essential hypertension) in patients using the same components as individual components, or when treatment with amlodipine alone did not lower your blood pressure enough.

3. BEFORE YOU TAKE TWYNSTA

Do not take TWYNSTA if you are pregnant, are considering becoming pregnant or are breastfeeding. A switch to a suitable alternative treatment should be carried out in advance of planned pregnancy.

Do not take TWYNSTA:

- if you are allergic to telmisartan, amlodipine or any of the other ingredients included in TWYNSTA tablets
- if you are allergic to other medicines of the dihydropyridine type (one type of calcium channel blocker)
- if you take any other products containing amlodipine
- if you suffer from a rare hereditary condition called fructose intolerance
- if you have developed swelling and giant wheals on your skin when having previously taken medicines called angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs)
- if you have a narrowing of the aortic blood vessel
- if both blood vessels to the kidneys are narrowed or if you have a single kidney and the blood vessel to the kidney is narrowed
- if you suffer from severe liver problems
- if you suffer from biliary obstruction (a problem with the drainage of the bile from the liver and gall bladder)
- if you suffer from porphyria
- if you are currently taking lithium or potassium sparing water tablets containing spironolactone, triamterene or amiloride
- if you suffer from low heart output because of a serious heart problem
- if you suffer from severe renal impairment
- if you are currently taking aliskiren-containing products

Take special care with TWYNSTA and tell your health care provider:

Please tell your health care provider if you are suffering or have ever suffered from any of the following conditions or illnesses:

- if you suffer from kidney disease or have ever had a kidney transplant
- if you suffer from liver problems
- if you have heart problems
- if you already take a medicine called an angiotensin-converting enzyme inhibitor (ACE)
- if you have been told that you have raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals)
- if you have low blood pressure (hypotension), which is 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
- if you have high potassium levels in your blood or use salt substitutes that contain potassium

- if you have diabetes.
- In case of surgery or anaesthesia, you should tell your health care provider that you are taking TWYNSTA.
- The use of TWYNSTA in children and adolescents up to the age of 18 years is not recommended.
- Contact your doctor to re-evaluate your treatment if you are treated with Angiotensin-converting enzyme (ACE) inhibitors/Angiotensin receptor blockers (ARBs) together with a fluoroquinolone antibiotic.

Taking TWYNSTA with food and drink:
You can take TWYNSTA with water or other non-alcoholic drink and with or without food.

Grapefruit and grapefruit juice:
You should not eat grapefruit or drink grapefruit juice when you take TWYNSTA because this can increase the blood pressure lowering effect in some people.

Pregnancy and breastfeeding:
Do not take TWYNSTA and tell your health care provider if you are pregnant, are considering becoming pregnant or are breastfeeding. A switch to a suitable alternative treatment should be carried out in advance of planned pregnancy.

Driving and using machinery:
No information is available on the effect of TWYNSTA on the ability to drive or operate machinery. 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 operate machinery.

Important information about some of the ingredients of TWYNSTA:
TWYNSTA contains sorbitol. If you have been told that you have an intolerance to some sugars, you should not take TWYNSTA.

Taking other medicines with TWYNSTA:
If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of TWYNSTA with these medicines may cause undesirable interactions. Please consult your health care provider for advice. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below when taken together with TWYNSTA:
- Digitalis glycosides (digoxin) which is a heart medication
- Lithium-containing medicines used to treat some types of depression
- Anticonvulsant agents (e.g. carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone)
- Rifampicin
- St. John's wort
- Medicines used for HIV/AIDS (e.g. ritonavir) or for treatment of fungal infections (e.g. ketoconazole, itraconazole)
- Simvasatin used to lower your cholesterol levels
- Ciclosporin or tacrolimus used to suppress your immune system

The effect of TWYNSTA may be reduced when you take NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin 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. antidepressants, barbiturates, narcotics) or alcohol.
TWYNSTA can interfere with ACE-inhibitors.

4. HOW TO TAKE TWYNSTA

Do not share medicines prescribed for you with any other person.

Always take TWYNSTA exactly as your health care provider has instructed you. You should check with your health care provider if you are unsure.

The usual dose of TWYNSTA is one tablet per day. Try to take the tablet at the same time each day.
Remove your TWYNSTA tablet from the blister only immediately prior to intake.

You can take TWYNSTA with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. It is important that you take TWYNSTA every day until your health care provider tells you otherwise. If you have the impression that the effect of TWYNSTA is too strong or too weak, talk to your health care provider.

If your liver is not working properly, the usual dose should not exceed TWYNSTA 40/5 mg or TWYNSTA 40/10 mg once daily.

If you take more TWYNSTA than you should:
In the event of overdosage or accidental intake, consult your health care provider. If he/she is not available, seek help at the nearest hospital or poison control centre.

If you forget to take TWYNSTA:
If you forget to take a dose, do not worry. Take it as soon as you remember on the same day. If you do not take your tablet on that same day, take your normal dose on the next day. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

TWYNSTA can have side effects.

Frequent side effects may include:
Dizziness, ankle swelling.

Less frequent side effects may include:
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, abdominal pain, diarrhoea, feeling sick (nausea), itching, joint pain, muscle cramps, muscle pain, back pain, inability to obtain an erection, weakness, chest pain, tiredness, swelling, increased levels of liver enzymes.

Rare side effects may include:
Bladder infection, depression, feeling anxious, sleeplessness, fainting, taste abnormalities, trembling, vomiting, swollen gums, discomfort in the abdomen, dry mouth, eczema (a skin disorder), redness of skin, rash, painful limbs, urge to urinate during the night, feeling unwell, increased levels of uric acid in the blood.

Telmisartan:
In patients taking telmisartan (one of the ingredients of TWYNSTA) alone the following additional side effects have been reported:

Less frequent side effects may include:
Urinary tract infections, upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold), deficiency in red blood cells (anaemia), high potassium levels, shortness of breath, bloating, increased sweating, increased levels of creatinine in the blood.

Rare side effects may include:
Sepsis (often called "blood poisoning" is a severe infection with whole body inflammatory response which can lead to death), increase in certain white blood cells (eosinophilia), low platelet count (thrombocytopenia), allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure), rapid swelling of skin and mucosa (angioedema) which may lead to death, low blood sugar (in diabetic patients), impaired vision, fast heart beat, stomach discomfort, abnormal liver function, hives (urticaria), rash, inflammation of the tendons, kidney impairment including acute kidney failure, flu-like illness, decreased haemoglobin (a blood protein), increased levels of creatine phosphokinase in the blood.

Amlodipine:
In patients taking amlodipine (one of the ingredients of TWYNSTA) alone the following additional side effects have been reported, but the frequencies are not known:
Low number of white cells in the blood, 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 (diabetes), mood changes, confusion, abnormal muscle movements, impaired vision, ringing in the ears, heart attack, irregular heart beat, inflammation of the blood vessels, shortness of breath, sneezing/running nose, change of bowel habit, inflamed pancreas, abdominal bloating (gastritis), inflammation of the liver, yellowing of the skin (jaundice), increased levels of liver enzymes with jaundice, hair loss, unusual bruising and bleeding (red blood cell damage), skin discolouration, increased sweating, rapid swelling of skin and mucosa (angioedema), severe skin reactions, hives (urticaria), peeling of the skin, Stevens-Johnson syndrome (rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals), increased sensitivity of the skin to the sun, difficulty passing urine, increased need to pass urine especially at night, enlarging of male breasts, pain, weight increased, weight decreased.

Not all side effects reported for TWYNSTA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TWYNSTA, please consult your health care provider for advice.

If you notice any side effects not mentioned in this leaflet, please inform your health care provider.

6. STORING AND DISPOSING OF TWYNSTA

Store at or below 30 °C in the original package in order to protect from light and moisture.
Remove your TWYNSTA tablet from the blister only immediately prior to intake.

Keep all medicines out of the reach and sight of children.

Do not take TWYNSTA after the expiry date stated on the blister strips and carton. The expiry date refers to the last day of that month. Return all unused or expired medicines to your health care provider for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF TWYNSTA

Printed cartons containing 28 tablets, packed in silver aluminium blister strips containing 7 tablets per strip.

8. IDENTIFICATION OF TWYNSTA

TWYNSTA 40/5 mg: Oval shaped, biconvex, bilayered uncoated tablets with one layer white to off-white and other layer blue, debossed with "Boehringer Ingelheim company symbol" and "A1" on white layer and plain on other side.

TWYNSTA 40/10 mg: Oval shaped, biconvex, bilayered uncoated tablets with one layer white to off-white and other layer blue, debossed with "Boehringer Ingelheim company symbol" and "A2" on white layer and plain on other side.

TWYNSTA 80/5 mg: Oval shaped, biconvex, bilayered uncoated tablets with one layer white to off-white and other layer blue, debossed with "Boehringer Ingelheim company symbol" and "A3" on white layer and plain on other side.

TWYNSTA 80/10 mg: Oval shaped, biconvex, bilayered uncoated tablets with one layer white to off-white and other layer blue, debossed with "Boehringer Ingelheim company symbol" and "A4" on white layer and plain on other side.

9. REGISTRATION NUMBERS

TWYNSTA 40/5 mg: 44/7.1.3/0857
TWYNSTA 40/10 mg: 44/7.1.3/0858
TWYNSTA 80/5 mg: 44/7.1.3/0859
TWYNSTA 80/10 mg: 44/7.1.3/0860

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Ingelheim Pharmaceuticals (Pty) Ltd
407 Pine Avenue
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South Africa

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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date of registration: 07 June 2012
Revised: 20 August 2019