

PART III: CONSUMER INFORMATIONPr **Twynsta**[®]

(Telmisartan/Amlodipine (as Amlodipine Besylate)) Tablets

Read this carefully before you start taking TWYNSTA and each time you get a refill. This leaflet is a summary and will not tell you everything about TWYNSTA. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about TWYNSTA.

ABOUT THIS MEDICATION**What the medication is used for:**

TWYNSTA is used to treat high blood pressure in patients who already receive telmisartan and amlodipine from separate tablets and who wish to take instead the same doses in one tablet for convenience.

What it does:

TWYNSTA contains a combination of 2 drugs, telmisartan and amlodipine:

- Telmisartan is an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”.
- Amlodipine is a calcium channel blocker.

These medicinal ingredients work together to lower blood pressure.

This medicine does not cure your disease. It helps to control it. Therefore, it is important to continue taking TWYNSTA regularly even if you feel fine.

When it should not be used:

Do not take TWYNSTA if you:

- Are allergic (hypersensitive) to telmisartan or amlodipine or to any non-medicinal ingredient in the formulation.
- Have experienced an allergic reaction (angioedema) with swelling of the hands, feet, or ankles, face, lips, tongue, throat, or sudden difficulty breathing or swallowing, to any ARB. Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.
- Are allergic to other medicines of the dihydropyridine type (one type of calcium channel blocker).
- Are pregnant or intend to become pregnant. Taking TWYNSTA during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. It is possible that TWYNSTA passes into breast milk.
- Have been diagnosed with hereditary fructose intolerance, a rare genetic disorder in which a person cannot break down fructose. TWYNSTA 80/5 mg and 80/10 mg tablets contain 337.28 mg of a similar type of sugar called sorbitol.
- Have severe liver problems or biliary obstruction (problems with drainage of the bile from the liver and gallbladder).

- Suffer from low heart output because of a serious heart problem.
- Are already taking a blood pressure-lowering medicine that contains aliskiren (such as Rasilez) and you have diabetes or kidney disease.

What the medicinal ingredients are:

Telmisartan and amlodipine (as amlodipine besylate)

What the non-medicinal 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, pregelatinized starch, sodium hydroxide, sorbitol.

What dosage forms it comes in:

Tablets: 40/5 mg, 40/10 mg, 80/5 mg, 80/10 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions - Pregnancy
TWYNSTA should not be used during pregnancy. If you discover that you are pregnant while taking TWYNSTA, stop the medication and contact your doctor, nurse, or pharmacist as soon as possible.

BEFORE you use TWYNSTA talk to your doctor or pharmacist if you:

- Have experienced an allergic reaction to any drug used to lower blood pressure.
- Have renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
- Have swelling of your legs.
- Have raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
- Are taking a medicine that contains aliskiren, such as Rasilez, used to lower high blood pressure. The combination with TWYNSTA is not recommended.
- Are taking an angiotensin-converting-enzyme inhibitor (ACEI).
- Have angina, narrowing of a heart valve or blood vessel, heart or blood vessel disease.
- Have diabetes mellitus, liver or kidney disease.
- Are on dialysis or have a kidney transplant.
- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- Are on a low-salt diet.
- Are taking a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill” that makes your body keep potassium).
- Are less than 18 years old.

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

Sorbitol:

TWYNSTA tablets 40/5 mg and 40/10 mg contain 168.64 mg sorbitol in each tablet.

Driving and using machines:

Before you perform tasks which may require special attention, wait until you know how you respond to TWYNSTA. Dizziness, lightheadedness, or fainting can especially occur after the first dose and when the dose is increased.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with TWYNSTA:

- Agents increasing serum potassium, such as a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”);
- Blood pressure lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. Rasilez), or angiotensin-converting-enzyme inhibitors (ACEI);
- Clarithromycin, an antibiotic used to treat infections;
- Lithium used to treat bipolar disease;
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ASA (Aspirin), ibuprofen, naproxen, and celecoxib;
- Corticosteroids taken by mouth or injection;
- Digoxin to treat heart conditions;
- Warfarin used to prevent blood clots (blood thinner);
- Anticonvulsant agents. Examples include carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone;
- Rifampicin, an antibiotic used to treat infections;
- Medicines used to treat HIV/AIDS. An example is ritonavir;
- Medicines used to treat fungal infections. Examples include ketoconazole, itraconazole;
- Atorvastatin and simvastatin used to lower cholesterol;
- Sildenafil (Viagra);
- St. John’s Wort;
- Immunosuppressants, such as ciclosporin and tacrolimus.

Lower than normal blood pressure may occur when TWYNSTA is given with the following:

- alcohol;
- antidepressants;
- barbiturates (sleeping pills);
- narcotics (strong pain medications);
- nitroglycerin or other nitrates.

PROPER USE OF THIS MEDICATION

Take TWYNSTA exactly as prescribed. It is recommended to swallow your dose whole with water at about the same time

everyday, preferably in the morning.

Take TWYNSTA with or without food, but it should be taken the same way each day.

Remove your TWYNSTA tablet from the blister just prior to intake.

Usual Adult Dose:

The usual dose of TWYNSTA is one tablet once a day.

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

Overdose:

If you think you have taken too much TWYNSTA contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you have forgotten to take your dose during the day, carry on with the next one at the usual time. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- dizziness, vertigo (feeling of spinning);
- drowsiness, insomnia, fatigue;
- urge to urinate during the night;
- rash, eczema, redness of skin, skin eruptions, itching, hives (urticaria), scaling of the skin (exfoliative dermatitis), increased sweating, drug rash, hair loss, skin discolouration, photosensitivity reaction;
- diarrhea, vomiting, constipation, nausea, upset stomach, abdominal pain, flatulence, change of bowel habit;
- taste abnormalities, enlarged gums;
- dry mouth;
- headache, migraine, anxiety, mood changes, ringing in the ears;
- sleepiness, sleeplessness, tiredness;
- back or leg pain, muscle cramps, joint pain, muscle spasms;
- visual disturbance;
- upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold), flu-like illness, cough, sneezing, runny nose, shortness of breath;
- inability to obtain an erection;
- enlarging of male breasts;
- weight increased, weight decreased.

If any of these affects you severely, tell your doctor, nurse or pharmacist.

TWYNSTA can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Ankle swelling (edema)	✓		
Uncommon	Shortness of breath	✓		
	Low blood pressure: dizziness, fainting, light-headedness, trembling, flushing. May occur when you go from lying or sitting to standing up.		✓	
	Slow heartbeat		✓	
	Palpitations (awareness of your heartbeat)		✓	
	Chest pain		✓	
	Tingling or numbness of hands or feet	✓		
	Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, muscle cramps, muscle wasting disease, pain, back pain, pain in extremity, inflammation of the tendons, dark brown urine		✓	
	Increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell		✓	
	Kidney Disorder including Acute Kidney Failure: change in frequency of urination (little or no urine), nausea, vomiting, swelling of extremities, fatigue		✓	

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Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
	Urinary Tract Infections (Cystitis): frequent or painful urination, feeling unwell	✓		
	Decreased Platelets: bruising, bleeding, fatigue and weakness		✓	
Rare	Depression: low mood, feeling sad, loss of interest in activities, change in appetite and sleep patterns		✓	
	Low blood sugar: shaky, irregular heartbeat, sweating, hunger, dizziness (in diabetic patients)		✓	
	Allergic reaction: rash, hives, rapid swelling of the face, lips, tongue or throat, difficulty swallowing or breathing with a potential fatal outcome			✓
	Sepsis (blood poisoning): chills, confusion, fever or low body temperature, shakiness, irregular heartbeat (including fatal outcome)			✓
	Confusional State		✓	
Unknown frequency	Stevens-Johnson syndrome: fever, sore throat, and fatigue followed by ulcers and other lesions to appear in the mouth and on lips but also in the genital and anal regions			✓
	Difficulty passing urine		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite, aches, tiredness, and a general ill feeling or flu-like symptoms		✓	
Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms		✓	
Anemia: fatigue, loss of energy, weakness, shortness of breath		✓	
Inflamed pancreas: abdominal pain radiating to the back, nausea and vomiting		✓	
Gastritis: nausea, vomiting, burping, bloating and feeling full after only a few bites of food		✓	
Increased blood sugar: frequent urination, thirst and hunger (in diabetic patients)		✓	
Inflammation of the blood vessels: fever, red raised spots caused by bleeding under the skin, aching muscles and joints, headache			✓
Irregular heartbeat		✓	
Fast heartbeat		✓	
Heart attack			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Extrapyramidal symptoms: muscle stiffness, body spasms, upward eye rolling, exaggeration of reflexes, drooling, difficulty moving how and when you want			✓

This is not a complete list of side effects. For any unexpected effects while taking TWYNSTA, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of reach and sight of children.

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

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

Store at 15 - 30°C.

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.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION**If you want more information about TWYNSTA:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), the manufacturer's website (<http://www.boehringer-ingelheim.ca>), or by calling the manufacturer, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 84633.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd. The information in this leaflet is current up to the time of the last revision date shown below, but more current information may be available from the manufacturer.

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