

**NEW FOR HYPERTENSION**

# APPROVED & AVAILABLE

TWYNSTA<sup>®</sup> (telmisartan/amlodipine) tablets are indicated for the treatment of hypertension, alone or with other antihypertensive agents.<sup>1</sup>

TWYNSTA may also be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals.<sup>1</sup>

**NEW**  
**TWYNSTA**<sup>®</sup>  
(telmisartan/amlodipine) tablets  
40/5 • 40/10 • 80/5 • 80/10 mg



#### IMPORTANT SAFETY INFORMATION

**WARNING: AVOID USE IN PREGNANCY**

When used in pregnancy, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus. When pregnancy is detected, TWYNSTA<sup>®</sup> (telmisartan/amlodipine) tablets should be discontinued as soon as possible (*See Warnings and Precautions*).

TWYNSTA is indicated for the treatment of hypertension, alone or with other antihypertensive agents. It may also be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals.

Please see enclosed full Prescribing Information, including boxed WARNING, for TWYNSTA. Please see further Important Safety Information on following pages.

**NEW FOR HYPERTENSION**

## New TWYNSTA available in 4 combination dose strengths<sup>1</sup>

Telmisartan/amlodipine equivalent



- Dosage may be individualized. The usual starting dose of TWYNSTA<sup>®</sup> (telmisartan/amlodipine) tablets is 40/5 mg once daily
- Patients requiring larger blood pressure reductions may be started on TWYNSTA 80/5 mg once daily. The maximum recommended dose of TWYNSTA is 80/10 mg once daily<sup>1</sup>

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In patients who are 75 years of age and older or hepatically impaired, amlodipine should usually be started or added at a dose of 2.5 mg.

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**NEW TWYNSTA NOW APPROVED**

## TWYNSTA Will Be Available in Your Pharmacy by Mid-November

	TWYNSTA 40/5 mg	TWYNSTA 40/10 mg	TWYNSTA 80/5 mg	TWYNSTA 80/10 mg
<b>National Drug Code (NDC)</b>	0597-0124-37	0597-0125-37	0597-0126-37	0597-0127-37
<b>Wholesale Acquisition Cost (WAC)</b>	\$105 per unit of sale	\$105 per unit of sale	\$105 per unit of sale	\$105 per unit of sale
<b>Package Size (Unit of Sale)</b>	Blister Pack 30's 3x10	Blister Pack 30's 3x10	Blister Pack 30's 3x10	Blister Pack 30's 3x10

Tablets shown are not actual size.

**Storage:** The recommended temperature for storing TWYNSTA<sup>®</sup> (telmisartan/amlodipine) tablets is 25°C (77°F), with excursions permitted to 15°C to 30°C (59°F to 86°F).

### IMPORTANT SAFETY INFORMATION

In patients with an activated renin-angiotensin system, such as volume- and/or salt-depleted patients, symptomatic hypotension may occur after initiation of therapy with TWYNSTA<sup>®</sup> (telmisartan/amlodipine) tablets. This condition should be corrected prior to administration of TWYNSTA, or treatment should start under close medical supervision with a reduced dose.

Since the vasodilation induced by amlodipine in TWYNSTA is gradual in onset, acute hypotension has rarely been reported after oral administration. Nonetheless, caution, as with any other peripheral vasodilator, should be exercised when administering amlodipine, particularly in patients with severe aortic stenosis.

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## IMPORTANT SAFETY INFORMATION

As the majority of telmisartan is eliminated by biliary excretion, patients with biliary obstructive disorders or hepatic insufficiency can be expected to have reduced clearance. TWYNSTA® (telmisartan/amlodipine) tablets should be used with caution in these patients.

Since amlodipine is extensively metabolized by the liver and the plasma elimination half-life ( $t_{1/2}$ ) is 56 hours in patients with impaired hepatic function, caution should be exercised when administering TWYNSTA to patients with severe hepatic impairment.

In patients whose renal function may depend on the activity of the renin-angiotensin-aldosterone system (eg, patients with severe CHF), treatment with angiotensin-converting enzyme inhibitors and angiotensin receptor antagonists has been associated with oliguria and/or progressive azotemia and (rarely) with acute renal failure and/or death. Similar results may be anticipated in patients treated with TWYNSTA.

In studies of ACE inhibitors in patients with renal artery stenosis, increases in serum creatinine or blood urea nitrogen were observed. An effect similar to that seen with ACE inhibitors should be anticipated with TWYNSTA.

Dual blockade of the renin-angiotensin-aldosterone system (eg, by adding an ACE inhibitor to an angiotensin II receptor antagonist) should be used with caution and should include close monitoring of renal function. Concomitant use of telmisartan and ramipril is not recommended.

Patients, particularly those with severe obstructive coronary artery disease, may develop increased frequency, duration, or severity of angina or acute myocardial infarction on starting calcium channel blocker therapy or at the time of dosage increase.

Closely monitor patients with heart failure.

In the placebo-controlled factorial design study, the most common reasons for discontinuation of therapy with TWYNSTA were peripheral edema, dizziness, and hypotension, each leading to discontinuation of  $\leq 0.5\%$  of TWYNSTA-treated patients. Adverse reactions that occurred at a  $\geq 2\%$  higher incidence on TWYNSTA than placebo were peripheral edema (4.8% vs 0%), dizziness (3.0% vs 2.2%), clinically meaningful orthostatic hypotension (6.3% vs 4.3%), and back pain (2.2% vs 0%).

**Reference:** 1. Twynsta PI. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; 2009.

TWYNSTA is a registered trademark of Boehringer Ingelheim International GmbH.

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