

INTRODUCING **NEW TWYNSTA**[®]

Dear Pharmacist:

Boehringer Ingelheim Pharmaceuticals, Inc. is pleased to announce the FDA approval of **New TWYNSTA[®] (telmisartan/amlodipine) tablets**. Fixed-dose combination TWYNSTA is an angiotensin II receptor blocker (ARB) and a dihydropyridine calcium channel blocker (DHP-CCB) combination product indicated for the treatment of hypertension, alone or with other antihypertensive agents. TWYNSTA may also be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals.¹

TWYNSTA is available in 4 combination dose strengths (telmisartan/amlodipine equivalent): 40/5 mg, 40/10 mg, 80/5 mg, and 80/10 mg.

Boehringer Ingelheim Pharmaceuticals, Inc. is supporting the launch of TWYNSTA with a promotional effort that includes:

- Sales force of over 775 representatives
- National Account Director and customer service support
- Direct-to-Pharmacy awareness campaign

Wholesalers will begin receiving **New TWYNSTA** in early November. It is anticipated that you will begin seeing prescriptions for TWYNSTA by mid-November.

Boehringer Ingelheim is proud to bring you this new formulation and appreciates your continued support.

Sincerely,



Robert Bellknap
*Executive Director
Trade Sales and Operations
Boehringer Ingelheim Pharmaceuticals, Inc.*

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[®] (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 next page.

NEW
TWYNSTA[®]
(telmisartan/amlodipine) tablets
40/5 • 40/10 • 80/5 • 80/10 mg



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® (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.

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 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%).

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.

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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40/5 • 40/10 • 80/5 • 80/10 mg

