PRESTALIA® (perindopril arginine and amlodipine) is available as white, uncoated tablets containing perindopril arginine 3.5 mg, 7 mg, or 14 mg and amlodipine 2.5 mg, 5 mg, or 10 mg for the following 3 combinations of perindopril arginine/amlodipine: 3.5/2.5 mg, 7/5 mg, or 14/10 mg. All 3 strengths are packaged in bottles of 90 tablets. Each tablet is debossed with tablet strength.[1]

PRESTALIA IS AVAILABLE THROUGH bpCareConnect, A HYPERTENSION MANAGEMENT PROGRAM FROM SYMPLMED

IMPORTANT SAFETY INFORMATION

When pregnancy is detected, discontinue PRESTALIA® as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

PRESTALIA is contraindicated in patients with hereditary or idiopathic angioedema, with or without previous angiotensin converting enzyme (ACE) inhibitor treatment, and in patients who are hypersensitive to perindopril, to ACE inhibitors, or to amlodipine. Rare cases of angioedema, including intestinal angioedema, have been reported in patients treated with ACE inhibitors. Do not co-administer aliskiren with ACE inhibitors, including PRESTALIA, in patients with diabetes.

Worsening angina and acute myocardial infarction can develop after starting or increasing the dose of PRESTALIA, particularly in patients with severe obstructive coronary artery disease. In patients at risk of excessive hypotension, start PRESTALIA therapy under close medical supervision. Follow patients closely for the first 2 weeks of treatment and whenever the dose of PRESTALIA is increased or a diuretic is added or its dose increased. Monitor renal function periodically in patients treated with PRESTALIA. Consider withholding or discontinuing therapy in patients who develop a clinically significant decrease in renal function.

The most common adverse events associated with PRESTALIA include peripheral edema, cough, headache, and dizziness.

References:

1. PRESTALIA® (perindopril arginine and amlodipine Tablets [package insert]. Cincinnati, OH: Symplmed, LLC; 2016.
2. Journal of the American Society of Hypertension 9(4) (2015) 266–274; Efficacy and safety of perindopril arginine + amlodipine in hypertension; William J. Elliott, MD, PhD[a], Jennifer Whitmore, BS[b], Jeffrey D. Feldstein, MD[b,c], and George L. Bakris, MD[d]. [a]Division of Pharmacology, Pacific Northwest University of Health Sciences, Yakima, WA, USA; [b]XOMA Corp., Berkeley, CA, USA; [c]Symplmed, Bend, OR, USA; and [d]ASH Comprehensive Hypertension Center, The University of Chicago Medicine, Chicago, IL, USA. Manuscript received November 30, 2014 and accepted January 17, 2015.

prestalia®
perindopril arginine/
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When monotherapy is inadequate or multiple drugs are likely needed to control high blood pressure...

PRESCRIBE THE SIMPLICITY OF A PROVEN SINGLE-PILL COMBINATION (SPC)

prestalia®
perindopril arginine/
amlodipine besylate tablets

PRESTALIA® (perindopril arginine and amlodipine)-the first SPC of perindopril arginine and amlodipine besylate for the treatment of hypertension.[1]

WARNING: FETAL TOXICITY

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- **Drugs that act directly on the renin-angiotensin system, can cause injury and death to the developing fetus**

Fixed-dose combinations (FDCs): A strong offense in chronic disease management[2]

According to *The American Journal of Medicine*[2]:

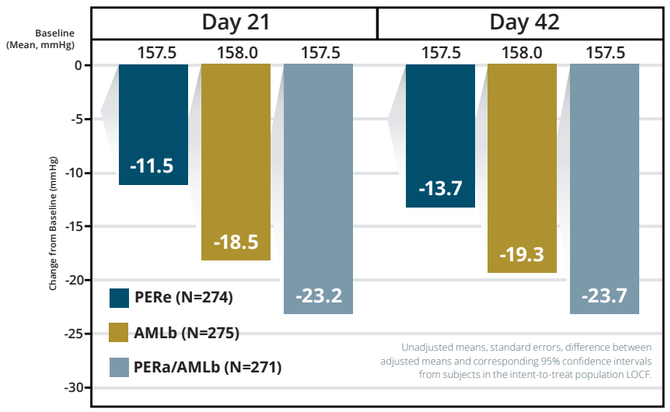
- Noncompliance to medication regimens is reduced by 24% to 26% with FDC regimens
- FDCs should be considered in patients with chronic conditions like hypertension
- FDCs improve medication compliance, which can translate into better clinical outcomes

Rapid and sustained BP control

The antihypertensive effects of PRESTALIA® (perindopril arginine and amlodipine) tablets were studied in the PATH (Perindopril and Amlodipine in Treatment of Hypertension) trial.[1] Peak efficacy was achieved by Week 3 and sustained to Week 6.

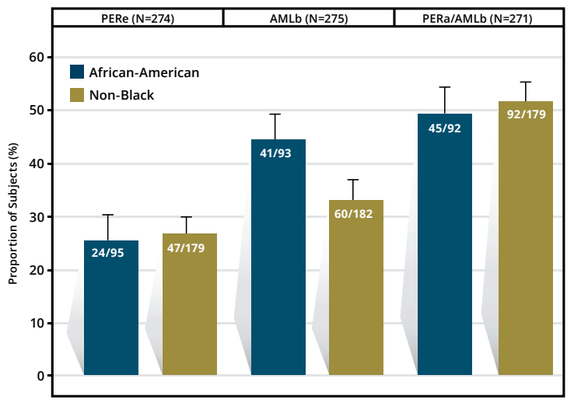
The highest strength of PRESTALIA (14/10) mg was studied in 837 patients in a 6-week, double-blind, active controlled clinical trial. Patients with a seated diastolic pressure of 95 mm to 115 mm Hg received treatments of PRESTALIA 14/10 mg, perindopril erbumine 16 mg, or amlodipine 10 mg once daily for 6 weeks.

Mean Change from Baseline in Sitting SBP



Effective FDC for African-American Population

Proportion of Responders* at Day 42 by Race[2]



Unadjusted proportions and standard errors from subjects in the intent-to-treat population.

***A subject is defined as a responder if they achieve a value of 140/90 mmHg, or 130/80 mmHg in subjects with diabetes (JNC 7).**

SAFETY AND DOSING

prestalia®
perindopril arginine/
amlodipine besylate tablets

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Adverse Events

Adverse Event	PRESTALIA 14/10 mg (N=279) / n (%)	perindopril erbumine 16 mg (N=278) / n (%)	amlodipine 10 mg (N=280) / n (%)
Edema peripheral	20 / (7.2)	1 / (0.4)	37 / (13.2)
Cough	9 / (3.2)	8 / (2.9)	2 / (0.7)
Headache	7 / (2.5)	8 / (2.9)	8 / (2.9)
Dizziness	7 / (2.5)	4 / (1.4)	3 / (1.1)

The safety of the maximum dose of PRESTALIA (14/10mg) was evaluated in a 6-week clinical trial 279 patients with hypertension and compared with perindopril erbumine 16 mg and amlodipine 10 mg. Adverse reactions were generally mild and transient in nature.[1]

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Reduction of CV events

Any reduction in blood pressure may reduce the incidence of heart attack, stroke and death. Both perindopril and amlodipine have proven in both placebo controlled trials and event trials to have an effect beyond just blood pressure reduction when compared to similar agents.[1]