

EXFORGE® Professional Fair Balance

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, EXFORGE (amlodipine and valsartan) should be discontinued as soon as possible. **See Warnings: Fetal/Neonatal Morbidity and Mortality.**

- EXFORGE is contraindicated in patients who are hypersensitive to amlodipine or valsartan.
- Excessive hypotension was seen in 0.4% of patients treated with EXFORGE. Volume and/or salt-depletion should be corrected in patients before administering EXFORGE or symptomatic hypotension may occur. Caution should be observed when initiating therapy in patients with heart failure or recent myocardial infarction and in patients undergoing surgery or dialysis.
- Rarely, increased frequency, duration, and/or severity of angina or acute myocardial infarction have developed in patients treated with calcium channel blockers; particularly patients with severe obstructive coronary artery disease.
- In patients with renal artery stenosis or severe renal impairment, care should be exercised with dosing of EXFORGE. In patients with severe HF, decline in renal function and rarely, acute renal failure and/or death has been associated with inhibiting the renin-angiotensin system.
- Dosage reduction and/or discontinuation of the diuretic and/or valsartan may be required. Evaluation of patients with heart failure or post-myocardial infarction should always include assessment of renal function.
- Amlodipine is not a beta-blocker and therefore gives no protection against the dangers of abrupt beta-blocker withdrawal; any such withdrawal should be by gradual reduction of the dose of beta-blocker.
- The most common adverse events that occurred more frequently with EXFORGE than placebo were peripheral edema (5% vs. 3%), nasopharyngitis (4% vs. 2%), upper respiratory tract infection (3% vs. 2%) and dizziness (2% vs. 1%).

EXFORGE is not indicated for the initial treatment of hypertension.

Please see accompanying full Prescribing Information.