

Indication and Important Safety Information

ATACAND is indicated for the treatment of heart failure (NYHA Class II-IV) in patients with left-ventricular systolic dysfunction (ejection fraction $\leq 40\%$) to reduce cardiovascular death and to reduce heart failure hospitalizations. ATACAND also has an added effect on these outcomes when used with an ACE inhibitor (see clinical trials).

ATACAND is contraindicated in patients who are hypersensitive to any component of this product.

USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus. When pregnancy is detected, ATACAND should be discontinued as soon as possible. See full PI WARNINGS, Fetal/Neonatal Morbidity and Mortality.

In heart failure patients receiving ATACAND, hypotension, increases in serum creatinine, and hyperkalemia have occurred. Caution should be observed for hypotension when initiating therapy. Evaluation of patients with heart failure should always include assessment of renal function and volume status. Monitoring of blood pressure, serum creatinine, and serum potassium is recommended during drug dose escalation and periodically thereafter.

Greater sensitivity of some older individuals (eg, >75 years) with heart failure must be considered.

During concomitant use of ATACAND and lithium, careful monitoring of serum lithium levels is recommended.

The adverse-event profile of ATACAND in heart failure patients was consistent with the pharmacology of the drug and the health status of the patients. In the CHARM program, comparing ATACAND in total daily doses up to 32 mg once daily ($n=3803$) with placebo ($n=3796$), 21.0% of patients discontinued ATACAND for adverse events vs 16.1% of placebo patients.

Please see accompanying full Prescribing Information, including boxed WARNING regarding use in pregnancy.

Reference: 1. Prescribing Information for ATACAND, Avapro (04/07), Benicar (10/06), Cozaar (12/05), Diovan (11/07), Micardis (5/06), and Teveten (8/07). 2. Granger CB, McMurray JJ, Yusuf S, et al., for the CHARM Investigators and Committees. Effects of candesartan in patients with chronic heart failure and reduced left-ventricular systolic function intolerant to angiotensin-converting-enzyme inhibitors: the CHARM-Alternative trial. *Lancet*. 2003;362:772-776.

www.atacand-us.com

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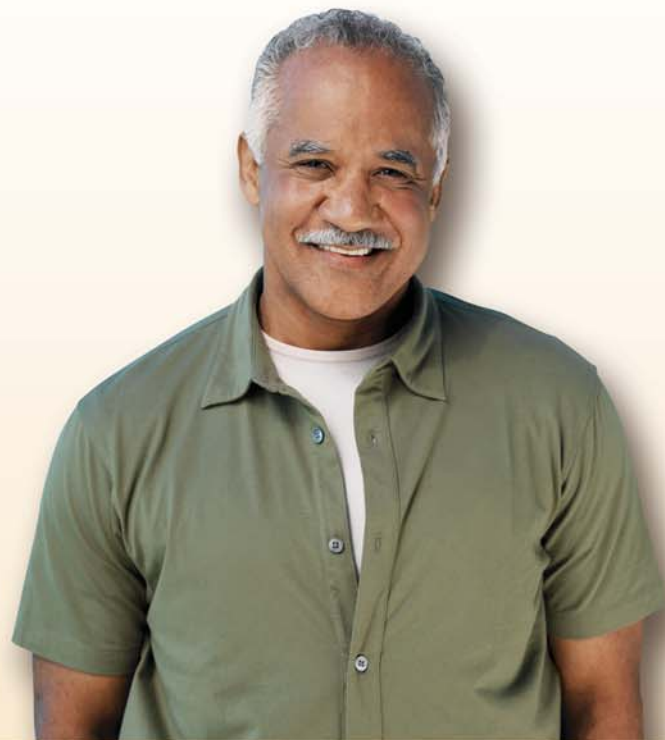
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*In patients with heart failure
(NYHA Class II-IV with LVEF $\leq 40\%$)*

**Diagnosis:
Heart Failure**



**ATACAND is the only ARB
proven to reduce CV death in
heart failure when added to
conventional HF therapies¹**

**Discontinue ATACAND as soon as possible
when pregnancy is detected.**

Please see accompanying full Prescribing Information,
including boxed WARNING regarding use in pregnancy.

NOT AN ACTUAL PATIENT



**In patients with heart failure
(NYHA Class II-IV with LVEF ≤40%)**

Name: Gerald Washington

Age: 58

Retired from a 23-year-long career with the US Army. Gerald lives in Baltimore, Maryland. He enjoys attending football games and working on his collection of classic American cars.

Height: 5'11"

Weight: 202

Medical history:

Diabetes, hypertension, prior myocardial infarction

CV exam results:

NYHA class: III

LVEF: 29%

Heart rate: 77 bpm and irregular

Blood pressure: 128/78 mm Hg

Medications:

Aspirin

β-blocker

Diuretic

Glimepiride

ACE inhibitor intolerant; reason:

Refractory cough

Gerald visited his doctor recently and was euvolemic, and complained of fatigue and frequent coughing.

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Please see accompanying full Prescribing Information, including boxed WARNING regarding use in pregnancy.



ATACAND provides significant reduction in the risk of CV death or hospitalization for HF when added to conventional HF therapy...*

CHARM-ALTERNATIVE TRIAL



Relative risk reduction[†] of CV death or HF hospitalization[‡] (P=.0004)²

Placebo + HF therapy without ACEI (n=406/1015) and ATACAND + HF therapy without ACEI (n=334/1013).

CHARM-Alternative was a double-blind, placebo-controlled study of 2028 subjects with NYHA Class II-IV HF, LVEF ≤40%, not receiving an ACEI due to intolerance, who were randomized to placebo or ATACAND (initially 4 or 8 mg once daily, titrated as tolerated to 32 mg once daily) on top of other conventional therapies. Median follow-up was 34 months.²

*Conventional HF therapies could include beta-blockers, spironolactone, diuretics, and digitalis

[†]Unadjusted hazard ratio 0.77 (95% CI 0.67-0.89)

[‡]Primary end point

Once-A-Day Tablets
Atacand[®]
candesartan cilexetil