Potassium sparing diuretics, potassium supplements or salt substitutes may lead to increases in pain, fatigue and hyperkalemia (6.1).


1. INDICATIONS AND USAGE

Valsartan is indicated for the treatment of hypertension, to lower blood pressure, usually in combination with diuretics. (2.1) It may be used alone or as part of a combination antihypertensive regimen, including with hydrochlorothiazide and chlorthalidone. (2.2) The antihypertensive effect is substantially present within 2 weeks and maximal reduction is generally achieved within 4 weeks. (2.3)

While antihypertensive effects of valsartan are not diminished when valsartan is administered with food, for convenience, the same dosage of valsartan may be taken at the same time of day whether or not the patient has eaten. Multiple-dose studies show that valsartan tablets are equally effective whether administered 12 hours apart or at the same time of day. (2.4)


1.2 Heart Failure

In controlled trials in hypertensive patients demonstrating risk reduction with valsartan tablets. (1.2) Reversal of the cardiovascular effects observed with valsartan has been reported in hypertensive patients (1.3). To explore the cardiovascular effects of valsartan in patients with heart failure or post-myocardial infarction, the Valsartan Heart Failure Trial (Val-HeFT) was conducted comparing valsartan to captopril. (1.4) Val-HeFT is a double-blind, randomized, placebo-controlled trial of 3188 patients with New York Heart Association (NYHA) Class II or III heart failure following myocardial infarction. (1.5)

The valsartan-atenolol combination was more antihypertensive than either component, but it did not lower the rate of progression of heart failure. (1.6) In a 3 month study, valsartan reduced the rate of progression of heart failure in comparison to placebo or captopril. (1.7) However, patients who received valsartan had a significantly reduced risk of death from all causes (1.8). The death rates were 20.4% for placebo, 18.1% for valsartan, and 16.4% for captopril (p <0.001). (1.9)

Valsartan has been used concomitantly with hydrochlorothiazide without evidence of clinically important drug interactions. (1.10) The combination of valsartan and hydrochlorothiazide is associated with a lower risk of ischemic stroke and death from all causes. (1.11)

If excessive hypotension occurs, the patient should be placed in the supine position and, if necessary, treated with vasopressors. Hypotension of greater than 50% may warrant the discontinuation of therapy. (1.12) Hypertension: (1.13) In general, avoid combined use of RAS inhibitors.

5.2 Hypotension

When pregnancy is detected, discontinue valsartan as soon as possible. (5.1) The use of antihypertensive drugs in late pregnancy may decrease the frequency of premature closure of the ductus arteriosus. (5.2) Post-Myocardial Infarction

Discontinuations occurred in 0.5% of valsartan-treated patients and 0.1% of placebo patients for each of the reasons listed. (16.1)

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Dual blockade of the RAS with angiotensin-converting enzyme inhibitors and angiotensin II receptor antagonists is not recommended either in pregnant women or women who may become pregnant. (1.16) There are no adequate and well-controlled studies in women who are pregnant, or in nursing women. (1.17) Therefore, valsartan should be reserved for the treatment of heart failure in pregnant patients only if clearly needed. (1.18)

In the Valsartan Heart Failure Trial (Val-HeFT), patients with New York Heart Association (NYHA) Class II or III heart failure were randomly assigned to valsartan or placebo in addition to standard therapy. (1.19) For a history of aortic stenosis, consider withhold or discontinue valsartan tablets. (1.20) For a history of renal artery stenosis, consider withhold or discontinue valsartan tablets. (1.21) For valve replacement or balloon angioplasty, withhold or discontinue valsartan tablets. (1.22)

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The antihypertensive effects of valsartan have been evaluated in two randomized, double-blind clinical trials (8.3). Valsartan, a non-peptide angiotensin II receptor antagonist, prevents the pressor effect of exogenous angiotensin II by competitive inhibition of angiotensin II binding to its specific receptor. The antihypertensive effects of valsartan have been evaluated in two randomized, double-blind clinical trials (8.3). Valsartan, a non-peptide angiotensin II receptor antagonist, prevents the pressor effect of exogenous angiotensin II by competitive inhibition of angiotensin II binding to its specific receptor. The antihypertensive effects of valsartan have been evaluated in two randomized, double-blind clinical trials (8.3). Valsartan, a non-peptide angiotensin II receptor antagonist, prevents the pressor effect of exogenous angiotensin II by competitive inhibition of angiotensin II binding to its specific receptor.

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Valsartan inhibits the pressor effect of angiotensin II infusions. An oral dose of 80 mg inhibits the pressor effect of angiotensin II to a similar extent in young and elderly normotensive men. Valsartan inhibits the pressor effect of angiotensin II infusions. An oral dose of 80 mg inhibits the pressor effect of angiotensin II to a similar extent in young and elderly normotensive men. Valsartan inhibits the pressor effect of angiotensin II infusions. An oral dose of 80 mg inhibits the pressor effect of angiotensin II to a similar extent in young and elderly normotensive men. Valsartan inhibits the pressor effect of angiotensin II infusions. An oral dose of 80 mg inhibits the pressor effect of angiotensin II to a similar extent in young and elderly normotensive men.

Valsartan has been shown to be effective in several clinical trials in patients with hypertension. In these studies, valsartan was administered once daily as monotherapy or in combination with other antihypertensive agents. The blood pressure lowering effect of valsartan and thiazide-type diuretics are approximately additive. The blood pressure lowering effect of valsartan and thiazide-type diuretics are approximately additive. The blood pressure lowering effect of valsartan and thiazide-type diuretics are approximately additive. The blood pressure lowering effect of valsartan and thiazide-type diuretics are approximately additive.

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