Candepressin

Candesartan cilexetil 8mg,16mg,32mg

Tablets

WARNING: FETAL TOXICITY

- **When pregnancy is detected, discontinue Candepressin as soon as possible** ***[see Warnings and Precautions (5.1) and Use in Specific Populations (8.1)].***
- **This drug should not be taken during pregnancy as it may lead to injury or death to the foetus.**

1 INDICATIONS AND USAGE

1.1 Hypertension

Candepressin is indicated for the treatment of hypertension in adults and in children 1 to <17 years of age, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and non-fatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from a wide variety of pharmacologic classes including the class to which this drug principally belongs.

Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake. Many patients will require more than one drug to achieve blood pressure goals. For specific advice on goals and management, see published guidelines, such as those of the National High Blood Pressure Education Program's Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC).

Numerous antihypertensive drugs, from a variety of pharmacologic classes and with different mechanisms of action, have been shown in randomized controlled trials to reduce cardiovascular morbidity and mortality, and it can be concluded that it is blood pressure reduction, and not some other pharmacologic property of the drugs, that is largely responsible for those benefits. The largest and most consistent cardiovascular outcome benefit has been a reduction in the risk of stroke, but reductions in myocardial infarction and cardiovascular mortality also have been seen regularly.

Elevated systolic or diastolic pressure causes increased cardiovascular risk, and the absolute risk increase per mmHg is greater at higher blood pressures, so that even modest reductions of severe hypertension can provide substantial benefit. Relative risk reduction from blood

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pressure reduction is similar across populations with varying absolute risk, so the absolute benefit is greater in patients who are at higher risk independent of their hypertension (for example, patients with diabetes or hyperlipidemia), and such patients would be expected to benefit from more aggressive treatment to a lower blood pressure goal.

Some antihypertensive drugs have smaller blood pressure effects (as monotherapy) in black patients, and many antihypertensive drugs have additional approved indications and effects (e.g., on angina, heart failure, or diabetic kidney disease). These considerations may guide selection of therapy.

Candepressin may be used alone or in combination with other antihypertensive agents.

1.2 Heart Failure

Candepressin is indicated for the treatment of heart failure (NYHA class II-IV) in adults with left ventricular systolic dysfunction (ejection fraction ≤ 40%) to reduce cardiovascular death and to reduce heart failure hospitalizations.

Candepressin also has an added effect on these outcomes when used with an ACE inhibitor.

2 DOSAGE AND ADMINISTRATION

the score line is to divide to 2 equal doses.

2.1 Adult Hypertension

Dosage must be individualized. Blood pressure response is dose related over the range of 2 to 32 mg. The usual recommended starting dose of Candepressin is 16 mg once daily when it is used as monotherapy in patients who are not volume depleted. Candepressin can be administered once or twice daily with total daily doses ranging from 8 mg to 32 mg. Larger doses do not appear to have a greater effect, and there is relatively little experience with such doses. Most of the antihypertensive effect is present within 2 weeks, and maximal blood pressure reduction is generally obtained within 4 to 6 weeks of treatment with Candepressin.

Use in Hepatic Impairment: Initiate with 8 mg Candepressin in patients with moderate hepatic insufficiency. Dosing recommendations cannot be provided for patients with severe hepatic insufficiency.

Candepressin may be administered with or without food.

If blood pressure is not controlled by Candepressin alone, a diuretic may be added. Candepressin may be administered with other antihypertensive agents.

2.2 Pediatric Hypertension 1 to < 17 Years of Age

Candepressin may be administered once daily or divided into two equal doses. Adjust the dosage according to blood pressure response. For patients with possible depletion of intravascular volume (e.g., patients treated with diuretics, particularly those with impaired renal function), initiate Candepressin under close medical supervision and consider administration of a lower dose.

Children 1 to < 6 years of age: