Patients with severe hepatic impairment should start amlodipine at 2.5 mg (CCB), and diuretics.

Patients ≥ 75 years of age should start amlodipine at 2.5 mg, which is recommended to be started at the same dose as for younger patients.

The usual regimens of therapy with Sevikar HCT® may be followed if patients are stable on their current regimen.

Renal Impairment

Patients with renal impairment should be started on amlodipine at a lower dose than recommended for patients with normal renal function. Patients with severe renal impairment should be started at a dose of 2.5 mg.

Other Antihypertensive Drugs:

Angiotensin Converting Enzyme (ACE) Inhibitors:

ACE inhibitors are usually avoided in patients with renal impairment, as they can exacerbate renal dysfunction. However, amlodipine can be used in combination with ACE inhibitors with caution.

Calcium Channel Blockers:

Calcium channel blockers should be used with caution in patients with renal impairment, as they can cause hypotension and renal failure.

Diuretics:

Diuretics should be used with caution in patients with renal impairment, as they can cause fluid and electrolyte imbalances.

Drug Interactions:

Hydrochlorothiazide

Hydrochlorothiazide is excreted primarily by the kidneys. Patients with renal impairment may require a lower dose of hydrochlorothiazide.

Other Antihypertensive Drugs:

Angiotensin II Receptor Blockers (ARB):

Calcium Channel Blockers (CCB):

Other Antihypertensive Drugs:

Non-steroidal Anti-inflammatory Drugs (NSAIDs):

Interventions to reduce the risk of hypotension and renal dysfunction are recommended in patients with renal impairment.

Other Antihypertensive Drugs:

Sympathomimetics:

Diuretics:

Other Antihypertensive Drugs:

Hyperuricemia may occur or frank gout may be precipitated in certain patients treated with Sevikar HCT® due to the olmesartan medoxomil component.

In post-marketing experience, increased alanine aminotransferase (ALT), aspartate aminotransferase (AST), or total bilirubin levels, and hyperglycemia have been reported in patients taking olmesartan months to years after drug initiation.

5.10 Sprue-like Enteropathy

Patients with a history of sprue-like enteropathy should be monitored closely while taking Sevikar HCT®.

5.11 Anaphylaxis

Anaphylaxis has been reported in patients taking olmesartan medoxomil. Patients with a history of anaphylactic or severe allergic reactions to any component of Sevikar HCT® should not take this medication.

5.12 Other Reactions

Other reactions that have been reported in patients taking olmesartan medoxomil include rashes, urticaria, angioedema, fever, increased AST, ALT, and bilirubin levels, and increased creatinine levels.

Sevikar HCT® was dizziness (1%).

In general, calcium channel blockers should be used with caution in patients with renal impairment, as they can cause hypotension and renal failure.

Although vasodilation attributable to amlodipine is generally gradual in onset, acute hypotension has rarely been reported in patients taking the drug.

The frequency of adverse reactions was similar between men and women in clinical trials of Sevikar HCT®.

In the controlled trial of Sevikar HCT®, patients were randomized to olmesartan medoxomil or placebo. The incidence of adverse reactions was generally similar between the two groups.

The most common adverse reactions reported in patients taking olmesartan medoxomil were headache, edema, and diarrhea.

5.4 Pregnancy

Sevikar HCT® is not recommended for use in pregnant women.

In general, calcium channel blockers should be used with caution in patients with renal impairment, as they can cause hypotension and renal failure.

Although vasodilation attributable to amlodipine is generally gradual in onset, acute hypotension has rarely been reported in patients taking the drug.

Premature infants and newborns:

No significant drug interactions were reported in studies in which children aged 2 and older were given olmesartan medoxomil and amlodipine.

There are, however, concerns with the credibility of the finding of an increased risk of aortic arch stenosis in children taking olmesartan medoxomil.

The following adverse reactions have been identified during post-marketing experience:

[Table of adverse reactions]

6.2 Post-Marketing Experience

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C6H6O3S.

monobenzenesulphonate. Its empirical formula is C20H25CIN2O5 (2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate,

The structural formula for amlodipine besylate is:

6 to 12 hours.

Amlodipine does not change sinoatrial nodal function or atrioventricular

flow without change in filtration fraction or proteinuria.

greater response than patients with mild hypertension (diastolic

of reduction in blood pressure with amlodipine is also correlated with

With chronic once daily oral administration, antihypertensive

olmesartan medoxomil > 40 mg giving > 90% inhibition at 24 hours.

40 mg inhibit the pressor effects of angiotensin I infusion. The

medoxomil, amlodipine, and hydrochlorothiazide) lower the blood

calcium concentration is not affected by amlodipine. Within the

smooth muscle are dependent upon the movement of extracellular

Whether this difference has clinical relevance is not yet known.

An AT2 receptor is found also in many tissues, but this receptor is not

principal pressor agent of the renin-angiotensin system, with effects

has more than a 12,500-fold greater affinity for the AT1 receptor than

a reaction also catalyzed by ACE. Because olmesartan does not inhibit

co-administration of an angiotensin II receptor antagonist tends to

absorption from the gastrointestinal tract.

As amlodipine is highly protein bound, hemodialysis is not likely to

vasopressors (such as phenylephrine) should be considered with

unresponsive to these conservative measures, administration of

monitoring should be instituted. Frequent blood pressure

has not been established. The oral LD50 of hydrochlorothiazide is

area under the curve and Cmax were 10% to 15% higher in

Pharmacokinetics of olmesartan medoxomil in women compared to

Olmesartan medoxomil doses of 2.5 to

Mouse Lymphoma Cell (mutagenicity) assay and the

nidulans

12.2 Developmental Toxicity

No reproductive studies have been conducted with the combination of

12.2.1 Fetal Toxicity

in black and non-black patients treated with Sevikar HCT® [see Use in

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