Sevikar® (amlodipine and olmesartan medoxomil) tablets

**1 USE OF THE INDIVIDUAL COMPONENTS OF SEVIKAR®**

The following adverse reactions have been identified during post-approval use of the individual components of Sevikar® for hypotension, oliguria, and death. When combined, hypotension, oliguria, and death were observed in 0.3% of patients treated with Sevikar®.

**2 PATIENTS AND MULTIPLE-DOSE EXPERIENCE**

The recommended initial dose of Sevikar® in patients with severe renal impairment (creatinine clearance <30 mL/min) is 5/20 mg.

**3 CLINICAL PHARMACOLOGY**

**3.1 Pharmacokinetics**

The safety and effectiveness of Sevikar® in pediatric patients have not been established and use is not recommended in children.

**3.2 Mechanism of Action**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**3.3 Clinical Studies**

Amlodipine is a dihydropyridine calcium channel blocker that causes dilation of peripheral resistance arteries, including those of the coronary, cerebral, and peripheral vascular systems. The effects on the vasculature are manifested as both a reduction in blood pressure and an increase in coronary blood flow.

**4 ADVERSE REACTIONS**

**4.1 Drug Interactions**

The following adverse reactions have been identified during post-approval use of the individual components of Sevikar® for hypotension, oliguria, and death. When combined, hypotension, oliguria, and death were observed in 0.3% of patients treated with Sevikar®.

**4.2 Laboratory Findings**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**5 WARNINGS AND PRECAUTIONS**

**5.1 Hypersensitivity Reactions**

**5.2 Special Populations**

**5.3 Pregnancy**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**5.4 Nursing Mothers**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**5.5 Effects on Laboratory Tests**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**5.6 Edema**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**6 USE IN SPECIFIC POPULATIONS**

**6.1 Pregnancy**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**6.2 Lactation**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**6.3 Children**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**6.4 Elderly Patients**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**6.5 Renal Impairment**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**6.6 Hepatic Impairment**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**7 ADVERSE REACTIONS**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**8 DRUG INTERACTIONS**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**9 NONCLINICAL TOXICOLOGY**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**10 CLINICAL PHARMACOLOGY**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**11 MONITORING PARAMETERS**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**12 PATIENT INFORMATION**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**13 CLINICAL STUDY DATA**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**14 PREPARATORY INSTRUCTIONS**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**15 DURATIONS OF TREATMENT**

Sevikar® tablets are formulated for oral administration in the following satisfactory.

**16 DISPOSITION**
known to be associated with cardiovascular homeostasis. Olmesartan concentrations of olmesartan were similar in young adults and the were studied in the elderly (≥65 years). Overall, maximum plasma.

11.3 Pharmacokinetics

The inhibitory effect was related to dose, with doses of olmesartan mg inhibit the pressor effects of angiotensin I infusion. The duration of electrocardiographic parameters were observed.

The volume of distribution of olmesartan is unknown.

Furthermore, the gastrointestinal tract. The absolute bioavailability of olmesartan bioactivated by ester hydrolysis to olmesartan during absorption from protein bound, hemodialysis is not likely to be of benefit.

2,3-carbonate. Its empirical formula is C29H30N6O6. -tetrazol-5-ylphenyl)benzyl]imidazole-5-carboxylate, cyclic

The antihypertensive efficacy of amlodipine has been demonstrated in a

In a prospective study in renal transplant patients, an

Olmesartan medoxomil.

Amlodipine.

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Sevikar® tablets are differentiated by tablet color/size and are debossed

Reduction in Seated Systolic/Diastolic Blood Pressure (mmHg):

Mean Change

Red

White

-15/-9

-30/-19

-25/-14

-14/-9

-11/-8

-10/-1

5/20 mg