Sevikar® (amlodipine and olmesartan medoxomil) tablets

II. INDICATIONS AND USAGE

Taiwan version: DSTW201506-04

General Considerations

with olmesartan medoxomil (or another angiotensin receptor 
has not been satisfactory.

In general, calcium channel blockers should be used 
related, there was a greater incidence in women than men associated 
(240 times the maximum recommended human dose (MRHD) on a 
was administered to pregnant rats at oral doses up to 1000 mg/kg/day

If oliguria or hypotension occurs, direct attention toward support 

Alternate routes of elimination should be considered in patients 

Other antihypertensive agents may be used in combination with 

In addition, the antihypertensive activity of Sevikar® and the 

5.6 Patients with Impaired Renal Function

5.7 Patients with Hepatic Impairment

These included hypotension, orthostatic hypotension, rash, pruritus,

6 ADVERSE REACTIONS

Amlodipine has been evaluated for safety in more than 11,000

administration of ethanol. The mean change in AUC and Cmax 

of Sevikar®, 20% (384/1940) were 65 years of age or older and 3%

5.3 Use in Elderly Patients

5.5 Use in Pediatric Patients

4 CONTRAINDICATIONS

5.4 Use in Patients with Renal Impairment

5.1 Use in Patients with Impaired Hepatic Function

5.2 Use in Patients with Renal Impairment

5.3 Use in Elderly Patients

5.4 Use in Patients with Renal Impairment

5.5 Use in Pediatric Patients

5.2 Use in Patients with Renal Impairment

4.3 Pregnancy

The antihypertensive effect of angiotensin II receptor antagonists,

Co-administration of NSAIDs, including selective COX-2 

8.3 Pediatric Use

8.1 Pregnancy

8.2 Lactation

8.2 Lactation

Use of drugs that act on the renin-angiotensin system during the

Severe, chronic diarrhea with substantial weight loss has been

8.2 Lactation

8.1 Pregnancy

8.2 Lactation

8.3 Pediatric Use

Severe, chronic diarrhea with substantial weight loss has been

8.3 Pediatric Use

Use of drugs that act on the renin-angiotensin system during the

These reactions are reported voluntarily from a population of
Olmesartan medoxomil, a prodrug, is hydrolyzed to olmesartan in methanol.

The structural formula for olmesartan medoxomil is:

\[
\text{2,3-dihydroxy-2-butenyl 4-(1-hydroxy-1-methylethyl)-}
\]

Olmesartan medoxomil is rapidly and completely bioactivated by ester hydrolysis to olmesartan during absorption from the gastrointestinal tract. The absolute bioavailability of olmesartan medoxomil is about 90%.

After oral administration, the peak plasma concentration (Cmax) of olmesartan is achieved in about 4 hours post-dose, averaging about 12/6 mmHg in the standing position. Steady-state levels are reached in about 3 days. Steady-state trough concentrations of olmesartan are generally lower than peak concentrations.

Olmesartan is eliminated almost entirely by renal excretion as inactive metabolites via hepatic metabolism. Elimination from the plasma is biphasic with a terminal elimination half-life of about 13 hours.

The peak plasma concentration of olmesartan is independent of the dose, and the magnitude of blood pressure reduction in black patients approached that observed for non-Black patients.

The peak and trough effect of this difference has clinical relevance is not yet known.

One study in which dosing was begun 2 (female) or 9 (male) weeks prior to mating.

Heart Failure

In patients with heart failure, the response to olmesartan medoxomil dosing of 2.5 mg once daily in black patients was approximately 32% smaller as compared to the response in non-Black patients, with a magnitude of blood pressure reduction of about 7/4 mmHg.

Elderly patients have decreased clearance of olmesartan medoxomil. Population pharmacokinetic analysis indicated that female patients had approximately 15% smaller clearances of olmesartan than male patients. This effect in black patients has been seen with ACE inhibitors, with lesser magnitude in black patients.