

## DESCRIPTION

**Cardon**® is a preparation of Losartan Potassium, an angiotensin-II receptor antagonist with antihypertensive activity mainly due to selective blockade of AT<sub>1</sub> receptors and the consequent reduced pressor effect of angiotensin-II. It does not bind to or block other hormone receptors or ion channels important in cardiovascular regulation. Furthermore, it does not inhibit ACE, the enzyme that degrades bradykinin and cause persistent cough. Therefore, **Cardon**® is suitable for the patients who are unable to tolerate ACE inhibitors because of persistent cough.

#### INDICATIONS

**Cardon**® is indicated in the treatment of all grades of hypertension. It may be used alone or in combination with other antihypertensive agents.

#### DOSAGE AND ADMINISTRATION

The usual dose is 50 mg once daily, in the management of hypertension; if necessary increased after several weeks to 100 mg daily in one or two divided doses. For elderly over 75 years, patients with moderate to severe renal impairment and intravascular volume depletion; initially 25 mg once daily is suggested.

### SIDE-EFFECTS

Side-effects are usually mild. Symptomatic hypotension may occur, particularly in patients with intravascular volume depletion (e.g. those taking high-dose diuretics). Hyperkalaemia occurs occasionally; angioedema has also been reported with some angiotensin-II receptor antagonists. Other side-effects are diarrhoea, dizziness, taste disturbance, myalgia, migraine, urticaria, pruritus, rash, altered liver function tests; rarely hepatitis, anaemia (in severe renal disease or following renal transplant).

#### **PRECAUTIONS**

In patients who are intravenously volume depleted (e.g. those treated with high dose diuretics), symptomatic hypotension may occur. These conditions should be corrected prior to administer losartan potassium or a lower starting dose (usually 25 mg) should be used. A lower dose should be considered for patients with a history of hepatic and renal impairment. **Cardon**® should not be used with potassium-sparing diuretics.

#### **USE IN PREGNANCY AND LACTATION**

Although there is no experience with the use of **Cardon®** in pregnant women, animal studies with losartan potassium have demonstrated fetal and neonatal injury and death, the mechanism of which is believed to be pharmacologically mediated through effects on the renin-angiotensin-aldosterone system. Therefore, **Cardon®** should not be used in pregnancy and if pregnancy is detected **Cardon®** should be discontinued as soon as possible. It is not known whether losartan potassium is excreted in human breast milk. However, significant level of this drug found in rat milk suggest that this should not be used during lactation.

#### DRUG INTERACTIONS

No drug interaction of clinical significance has been identified. Compounds which have been studied in clinical pharmacokinetic trials include hydrochlorothiazide, digoxin, warfarin, cimetidine, ketoconazole and phenobarbital.

#### PHARMACEUTICAL PRECAUTION

Do not store above 30 °C. Keep away from light and wet place. Keep out of reach of children.

#### PACKAGING

#### Cardon® 25 tablet:

Box containing 3 strips of 10 film coated tablets each. Each tablet contains Losartan Potassium USP 25 mg.

#### Cardon® 50 tablet:

Box containing 4 strips of 10 film coated tablets each. Each tablet contains Losartan Potassium USP 50 mg.

# SK+F

Manufactured by

#### **ESKAYEF PHARMACEUTICALS LTD.**

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