דצמבר 2019

רופא/ה נכבד/ה
רוקח/ת נכבד/ה שלום רב,

Atacand 4 mg, 8 mg, 16 mg tablets : פרסום עדכון בעלון התכשיר

הרכב:

Each tablet contains 4 mg, 8 mg or 16 mg candesartan cilexetil.

Excipient with known effect:

4 mg: Each tablet contains 93.4 mg lactose monohydrate

8 mg: Each tablet contains 89.4 mg lactose monohydrate

16 mg: Each tablet contains 81.4 mg lactose monohydrate

התוויה:

Hypertension

Treatment of patients with heart failure and impaired left ventricle systolic function (left ventricular ejection fraction ≤ 40%) as add-on therapy to ACE inhibitors or when ACE inhibitors are not tolerated (see section 5.1 Pharmacodynamic properties).

חברת אסטרהזניקה ישראל מבקשת להודיע על עדכון עלון בהתאם להוראות משרד הבריאות בתאריך **דצמבר 2019.**

העדכון העיקרי בעלון לרופא הוא:

4.4 Special warnings and precautions for use

Renal impairment

As with other agents inhibiting the renin-angiotensin-aldosterone system, changes in renal function ~~including acute renal failure~~ may be anticipated in susceptible patients treated with Atacand.

General

In patients whose vascular tone and renal function depend predominantly on the activity of the renin-angiotensin-aldosterone system (e.g. patients with severe congestive heart failure or underlying renal disease, including renal artery stenosis), treatment with other medicinal products that affect this system has been associated with acute hypotension, azotaemia, oliguria or, rarely, acute renal failure.

The possibility of similar effects cannot be excluded with AIIRAs As with any antihypertensive agent, excessive blood pressure decrease in patients with ischaemic cardiopathy or ischaemic cerebrovascular disease could result in a myocardial infarction or stroke.

The antihypertensive effect of candesartan may be enhanced by other medicinal products with blood pressure lowering properties, whether prescribed as an antihypertensive or prescribed for other indications.

4.8 Undesirable effects

Treatment of Hypertension

System Organ Class	Frequency	Undesirable Effect
Gastrointestinal disorders	Very rare	Nausea
	Not known	Diarrhoea

Treatment of Heart Failure

System Organ Class	Frequency	Undesirable Effect
Gastrointestinal disorders	Very rare	Nausea
	Not known	Diarrhoea

4.9 Overdose

Management

If symptomatic hypotension should occur, symptomatic treatment should be instituted and vital signs monitored. The patient should be placed supine with the legs elevated. If this is not sufficient, plasma volume should be increased by infusion of, for example, isotonic saline solution.

Sympathomimeticmedicinal products may be administered if the above-mentioned measures are not sufficient.

~~Candesartan is not removed by haemodialysis.~~

5. PHARMACOLOGICAL PROPERTIES

5.2 Pharmacokinetic properties

Absorption and distribution

Following oral administration, candesartan cilexetil is converted to the active substance candesartan. The absolute bioavailability of candesartan is approximately 40% after an oral solution of candesartan cilexetil.

The relative bioavailability of the tablet formulation compared with the same oral solution is approximately 34% with very little variability. The estimated absolute bioavailability of the tablet is therefore 14%. The mean peak serum concentration (Cmax) is reached 3-4 hours following tablet intake. The candesartan serum concentrations increase linearly with increasing doses in the therapeutic dose range. No gender related differences in the pharmacokinetics of

candesartan have been observed. The area under the serum concentration versus time curve (AUC) of candesartan is not significantly affected by food.

העדכון העיקרי בעלון לצרכן הוא:

4. תופעות לוואי

תופעות לוואי ששכיחותן אינה ידועה (תופעות ששכיחותן טרם נקבעה)
שלשול

העלונים מפורסמים במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום.

בכבוד רב,
קארין קנבל דובסון

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