AstraZeneca

STUDY ABSTRACT

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Atacand (candesartan cilexetil) 16mg
ACTIVE INGREDIENT: candesartan cilexetil 16 mg

Study No: NIS-CRO-ATA-2007/1
Study PERFORM
Non-interventional study for the assessment of treatment efficacy of candesartan cilexetil on patients with uncontrolled arterial hypertension through reduction of arterial systolic and diastolic tension after 8 weeks of treatment.

Developmental Phase: post marketing. non-interventional observational study

Study Completion Date: February 2008

Date of Report: November 2010

OBJECTIVES:

Primary objective:

The purpose of this study was to observe prospectively treatment outcomes, as improvement of achieving treatment goals and impact on blood pressure level in patients with uncontrolled hypertension already on treatment with candesartan cilexetil.

Secondary objective:

Treatment compliance evaluation.

METHODS:

Noninterventional prospective study, included 1940 de patients treated with candesartan cilexetil 16 mg, and evaluated as essential arterial hypertension, uncontrolled.

The patients were treated and assessed according to current clinical practice for a period of 8 weeks (concomitant medication, heart rate, height, weight, blood pressure and concomitant diseases).

End-point: mean variations of systolic and diastolic blood pressure from enrolment (visit 1) to week 8 (visit 3).

No safety objective was included in this noninterventional project.

A written consent for data review and processing was obtained from each patient.

Inclusion Criteria:

- Diagnosis of essential hypertension (**mild** – systolic = 140–159 mmHg / diastolic = 90–99 mmHg or **moderate** – systolic = 160–179 mmHg / diastolic = 100–109 mmHg, as defined in European Guidelines of Hypertension, 2003), that are treated already with candesartan cilexetil 16mg o.d. within last 2 weeks or more.

Exclusion Criteria:

- patients who have any contraindication to the product as detailed in Romanian approved Atacand SPC.
- use of specific concomitant medication known to present a potential safety concern according to Romanian approved SPC
- hypersensitivity to the candesartan cilexetil or to any of the other excipients;
- pregnancy and lactation;
- severe hepatic impairment and / or cholestasis;
- children or adolescents (age below 18 years).
- treatment with other medications that could endanger the safety of candesartan cilexetil

RESULTS:

Subject population:

Characteristic		Statistic n (%)
Sex	male	931 (48.2)
	female	999 (51.2)
Hypertension	mild	706 (36.7)
	moderate	1021 (53.0)
	severe	199 (10.3)
Weight status	underweight	7 (0.4)
	normal weight	324 (16.7)
	overweight	907 (46.8)
	obese	687 (35.4)
Systolic blood pressure at visit 1	mean	160.9
	std. deviation	15.97
Diastolic blood pressure at visit 1	mean	94.77
	std. deviation	10.35
Concomitant diseases	atherosclerotic cerebrovascular disease	285 (14.7)
	coronary artery disease	1047 (54.0)
	diabetes mellitus	520 (26.8)

Concomitant therapy

Characteristic	Statistic n (%)
Angiotensin converting enzyme inhibitors (ACEI)	402 (20.7)
β blocker	959 (49.4)
Ca blocker	518 (26.7)
diuretic	1140 (58.8)
α blocker	12 (0.6)

Effect of treatment with 16 mg de candesartan cilexetil (blood pressure) - mm Hg

	visit 1 (n = 1940)		visit 2 (n = 1940)		visit 3 (n = 1939)	
	TAS	TAD	TAS	TAD	TAS	TAD
Mean	160.9	94.78	142.6	84.85	134.1	79.94
Std. Deviation	15.98	10.35	12.36	8.40	10.25	7.65

Mean variation of systolic blood pressure between:

- visit 2 (study week 4) vs baseline value: -18.32 ± 12.7 mm Hg
- visit 3 (study week 8) vs visit 2 (study week 4): -8.51 ± 9.35 mm Hg
- visit 3 (study week 8) vs baseline value: -26.83 ± 16.69 mm Hg.

- Mean variation of diastolic blood pressure between
- visit 2 (study week 4) vs baseline value: -9.9 ± 8.1 mm Hg
- visit 3 (study week 8) vs visit 2 (study week 4): -4.9 ± 6.15 mm Hg
- visit 3 (study week 8) vs baseline value: -14. 83 ± 9.69 mm Hg.

Treatment compliance (assessed by physician):

- 1858 (95.8%) patients had a treatment compliance of 80-100%;
- 78 (4%) patients had a treatment compliance of 50-79%
- 4 (0.2%) patients had a treatment compliance < 50%

No serious adverse events were reported.
No discontinuation due to adverse events had occurred.