13 July 2010
EMEA/CHMP/169828/2010 rev.
EMEA/H/A-30/1150

Questions and answers on Atacand and associated names (candesartan cilexetil 2, 4, 8, 16 and 32 mg tablets)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

The European Medicines Agency has completed a review of Atacand and associated names. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that there is a need to harmonise the prescribing information for Atacand in the European Union (EU).

What is Atacand?

Atacand is a medicine used to treat essential hypertension (high blood pressure) in adults. 'Essential' means that the hypertension has no obvious cause. It is also used to treat heart failure in adult patients with impaired left ventricular systolic function who are receiving treatment with 'angiotensin converting enzyme (ACE) inhibitors' or who cannot be given ACE inhibitors.

The active substance in Atacand, candesartan cilexetil, is an 'angiotensin II receptor antagonist', which means that it blocks the action of a hormone in the body called angiotensin II. Angiotensin II is a powerful vasoconstrictor (a substance that narrows blood vessels). By blocking the receptors to which angiotensin II normally attaches, candesartan cilexetil stops the hormone having an effect, allowing the blood vessels to widen. This helps blood pressure to drop, which also makes it easier for the heart to pump out blood.

Atacand is also available in the EU under other trade names: Amias, Blopress, Kenzen, Parapres, Racanda and Ratacand. The companies that market these medicines are AstraZeneca and Takeda.

Why was Atacand reviewed?

Atacand is authorised in the EU via national procedures. This has led to divergences among Member States in the way the medicine can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

Atacand was identified as needing harmonisation by the Co-ordination Group on the Mutual and Decentralised Procedures – Human (CMD(h)).

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On 16 July 2009, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Atacand in the EU.

What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

Some Member States had not approved the 32 mg dose for treating hypertension and there were differences in how heart failure was defined. The CHMP recommended that Atacand should be used to treat adult patients with:

- essential hypertension;
- heart failure and impaired left ventricular systolic function as 'add-on' therapy to ACE inhibitors or when ACE inhibitors are not tolerated.

4.2 Posology and method of administration

The recommended starting dose for treating hypertension is 8 mg once a day, which can be increased to a maximum of 32 mg once a day, depending on how the patient's blood pressure responds. For heart failure, the starting dose is 4 mg once a day, which can also be increased at intervals of at least two weeks up to a maximum of 32 mg once daily.

4.3 Contra-indications

The Committee recommend that Atacand must not be used in patients who are hypersensitive (allergic) to candesartan cilexetil or to any of the ingredients. It must also not be given to women in their second or third trimesters of pregnancy or to patients with severe liver impairment or cholestasis (problems with the elimination of bile).

4.4 Special warnings

There were little differences among Member States in the special warnings section. The Committee harmonised the warning on hyperkalaemia (high blood potassium levels) across all Member States' SmPCs.

The amended information to doctors and patients is available here.

The European Commission issued a decision on 13 July 2010.

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Referral start date:	23 July 2009
Company responses provided on:	8 October 2009, 12 February 2010
Opinion date:	18 March 2010