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Questions and answers on Atacand Plus and associated names (candesartan cilexetil/hydrochlorothiazide tablets 8/12.5 mg, 16/12.5 mg, 32/12.5 mg and 32/25 mg)

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

The European Medicines Agency has completed a review of Atacand Plus 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 Plus in the European Union (EU).

What is Atacand Plus?

Atacand Plus is a medicine that contains two active substances candesartan cilexetil and hydrochlorothiazide. It is used to treat essential hypertension (high blood pressure). 'Essential' means that the hypertension has no obvious cause.

Candesartan 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 stops the hormone having an effect, allowing the blood vessels to widen and blood pressure to fall.

Hydrochlorothiazide is a diuretic, which is another type of treatment for hypertension. It works by increasing urine output, reducing the amount of fluid in the blood and reducing blood pressure. The combination of the two active substances has an additive effect, reducing the blood pressure more than either medicine alone.

Atacand Plus is also available in the EU under other trade names: Atacand Plus Forte, Atacand Plus Mite, Atacand Zid, Blopresid, Blopress, Blopress Comp, Blopress Forte, Blopress Plus, CoKenzen, Hytacand, Parapres Comp, Parapres Comp Forte, Parapres Plus and Ratacand Plus.

The companies that market these medicines are AstraZeneca and Takeda.

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Why was Atacand Plus reviewed?

Atacand Plus is authorised in the EU via national procedures. This has led to divergences across 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 Plus was identified as needing harmonisation by the Co-ordination Group on the Mutual and Decentralised Procedures – Human (CMD(h)). On 27 October 2009, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Atacand Plus 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

The CHMP recommended that Atacand Plus be used to treat essential hypertension in adults whose blood pressure is not optimally controlled by candesartan cilexetil or hydrochlorothiazide alone.

4.2 Posology and method of administration

Atacand Plus should be taken at a dose of one tablet once a day. Dose titration is recommended. This means that the doctor should try different tablet strengths until the strength that adequately controls the patient's blood pressure is found.

4.3 Contra-indications

Atacand Plus must not be used in patients who are hypersensitive (allergic) to the active substances, any of the other ingredients or to substances derived from sulfonamide. It must also not be given to women in their second or third trimesters of pregnancy or to patients with severe kidney or liver problems, cholestasis (problems with the elimination of bile), gout (a painful inflammation of the joints) and hypokalaemia (low blood potassium levels) or hypercalcaemia (high blood calcium levels).

Other changes

The Committee also harmonised other sections of the SmPC including sections on special warnings, interactions with other medicines and pregnancy and lactation.

The amended information to doctors and patients is available here.

The European Commission issued a decision on 16 September 2010.

Rapporteur:	Pieter de Graeff (The Netherlands)
Co-rapporteur(s):	Alar Irs (Estonia)
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