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Questions and answers on Vascace Plus and associated names (cilazapril/hydrochlorothiazide tablets, 5/12.5 mg)

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

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

What is Vascace Plus?

Vascace Plus is a medicine that contains the active substances cilazapril and hydrochlorothiazide. It is used to treat hypertension (high blood pressure).

Cilazapril is an 'angiotensin converting enzyme (ACE) inhibitor'. It blocks the action of the enzyme ACE, which is responsible for the production of a hormone in the body called angiotensin II. Angiotensin II is a powerful vasoconstrictor (a substance that narrows blood vessels). By blocking the production of this hormone, cilazapril allows the blood vessels to widen, thereby reducing blood pressure.

Hydrochlorothiazide is a diuretic. It works by increasing urine output, reducing the volume of fluid in the blood and lowering the blood pressure. The combination of the two active substances has an additive effect, reducing the blood pressure more than either medicine alone.

Vascace Plus is also available in the EU under other trade names: Co-Inhibace, Dynorm Plus, Inhibace Plus and Inibace Plus.

The company that markets these medicines is F. Hoffmann – La Roche Ltd.

Why was Vascace Plus reviewed?

Vascace 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.

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

On 20 November 2009, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Vascace 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 Vascace Plus should be used for the treatment of hypertension in patients whose blood pressure is not adequately controlled with cilazapril alone.

4.2 Posology and method of administration

The recommended dosage of Vascace Plus is one tablet administered once daily.

4.3 Contra-indications

Vascace Plus should not be used in patients who are hypersensitive (allergic) to cilazapril or other ACE inhibitors, hydrochlorothiazide or other thiazides diuretics, or to any other ingredients of the medicine. It must not be used in patients with a history of angioedema (swelling beneath the skin) associated with previous treatment with ACE inhibitor, in patients with hereditary or idiopathic angioedema or in patients with kidney impairment or anuria (a condition in which a patient cannot make or pass urine). It must also not be used in the second and third trimesters (the last six months) of pregnancy.

Other sections

Other sections of the prescribing information such as those on special warnings, interactions with other medicines, and pregnancy and lactation and side effects were also harmonised.

The amended information to doctors and patients is available here.

The European Commission issued a decision on 21 January 2011.