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Questions and answers on Vascace and associated names (cilazapril, 0.5, 1, 2.5 and 5 mg tablets)

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

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

What is Vascace?

Vascace is a medicine that contains the active substance cilazapril. It is used to treat hypertension and long-term heart failure (inability of the heart to pump enough blood around the body).

The active substance in Vascace, 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, reducing the blood pressure. The reduced blood pressure also helps patients with heart failure, because it is easier for the heart to pump out blood if the pressure in the blood vessels is not too high.

Vascace is also available in the EU under other trade names: Dynorm, Inhibace, Inibace, Justor and Vascase.

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

Why was Vascace reviewed?

Vascace 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.

Vascace 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 September 2009, European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Vascace 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. Some of the areas harmonised include:

4.1 Therapeutic indications

The CHMP agreed that Vascace should be used for the treatment of hypertension and chronic heart failure.

4.2 Posology and method of administration

For hypertension, the recommended starting dose is 1 mg per day, which can be adjusted depending on how the patient's blood pressure responds. The usual dose is 2.5 to 5 mg per day.

A lower starting dose of 0.5 mg is recommended for hypertension in patients with a highly activated 'renin-angiotensin-aldosterone system' as they may experience an excessive drop in blood pressure. Treatment with diuretics (medicines that help increase the amount of water removed from the body in the urine) should, where possible, be stopped two to three days before starting treatment with Vascace.

For heart failure, the recommended starting dose is 0.5 mg once a day for one week. If this dose is well tolerated by the patient, it can be increased to 1 or 2.5 mg once a day.

Vascace should be taken once a day at about the same time each day. Patients with impairment of kidney function may have to take lower doses.

4.3 Contra-indications

The Committee recommended that Vascace should not be used in patients who are hypersensitive (allergic) to cilazapril or to any other ingredients of the product, or to other ACE inhibitors. It must not be used in patients with angioedema (swelling beneath the skin) associated with previous treatment with ACE inhibitor or in patients with hereditary or idiopathic angioedema. It must also not be used in the second and third trimesters (the last six months) of pregnancy.

Other changes

Other sections such as those on special warnings, interactions and pregnancy and lactation were also harmonised.

The amended information to doctors and patients is available here.

The European Commission issued a decision on 7 July 2010.

Rapporteur:	Alar Irs (Estonia)
Co-rapporteur(s):	János Borvendég (Hungary)
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