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Questions and answers on Norvasc and associated names (amlodipine, 5 and 10 mg tablets and capsules)

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

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

What is Norvasc?

Norvasc is medicine that contains the active substance amlodipine. It has been used to treat cardiovascular problems such as hypertension (high blood pressure) and angina (chest pain caused by problems with the blood flow to the heart).

Amlodipine is a calcium channel blocker. It blocks special channels on the surface of cells called calcium channels, through which calcium particles normally enter. When calcium enter the cells in the muscles of blood vessel walls, this causes contraction. By reducing the flow of calcium into the cells, amlodipine prevents the blood vessel walls from contracting, thus lowering the blood pressure for patients with hypertension and helping to make it easier for patients with heart problems to pump blood around the body.

Norvasc is also available in the EU under other trade names: Amlodipine Pfizer, Amlodipino, Amlor, Istin, Monopina, and Norvasc.

The company that markets these medicines is Pfizer.

Why was Norvasc reviewed?

Norvasc 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.

On 2 February 2011, Pfizer referred the matter to the CHMP in order to harmonise the SmPCs as well as to standardise the test used for examining the quality of Norvasc in the EU.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.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

Norvasc had been used to treat hypertension and angina in all EU countries. A type of angina called vasospastic or Prinzmetal's angina was approved in all EU countries except Denmark and Sweden, while coronary artery disease was approved in Latvia and Romania.

The CHMP harmonised the indications, recommending that Norvasc be used for: hypertension, chronic stable angina and vasospastic or Prinzmetal's angina.

4.2 Posology and method of administration

Dosing instructions were already harmonised in all EU countries, however, not all countries had dosing recommendations for Norvasc when used together with other medicines.

The CHMP has recommended that no dose adjustments for Norvasc are required when used together with the following antihypertensive medicines: thiazide, beta blockers, and angiotensin-converting enzyme (ACE) inhibitors.

4.3 Contra-indications

The CHMP harmonised the contraindication as follows: hypersensitivity (allergy) to dihydropyridine derivatives, amlodipine or to any of the excipients; severe hypotension (low blood pressure), shock (a steep fall in blood pressure), obstruction of the outflow tract of the left ventricle (a chamber in the heart) and patients with heart failure following a heart attack.

Other changes

The CHMP also harmonised other sections of the SmPC including sections 4.5 (interaction with other medicinal products and other forms of interaction) and 5.1 (pharmacodynamic properties)

The amended information to doctors and patients is available here.

European Commission issued a decision on 7 October 2011.