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Questions and answers on Plendil and associated names (felodipine 2.5, 5 and 10 mg prolonged release tablets)

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

On 23 October 2014, the European Medicines Agency completed a review of Plendil and associated names. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for Plendil and associated names in the European Union (EU).

What is Plendil?

Plendil is a medicine used to treat hypertension (high blood pressure). It is also used to treat angina pectoris (chest pain that occurs due to problems with the blood flow to the heart). Plendil contains the active substance felodipine. The medicine is available as prolonged release tablets (2.5, 5 and 10 mg) which release the active substance over an extended period of time.

Plendil and associated names have been authorised in EU Member States through national procedures since 1987.

Plendil and associated names are currently marketed in the following Member States of the EU: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Spain, Sweden and United Kingdom, as well as in Iceland and Norway.

The company that markets these medicines is AstraZeneca.

Why was Plendil reviewed?

As Plendil has been 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 differences in the SmPCs (summary of product characteristics), labelling and package leaflets in the countries where the medicine is marketed.

In view of this, on 12 November 2013 the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Plendil in the EU.

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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 for Plendil should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

After reviewing the available data supporting the medicine's use, the CHMP agreed that Plendil can be used to treat the following:

- hypertension;
- stable angina pectoris (a type of angina pectoris that occurs with activity or stress).

The Committee also agreed that Plendil should no longer be recommended to treat 'vasospastic angina pectoris' (another type of angina pectoris caused by spasms in the vessels supplying blood to the heart), because the available data to support this use were considered too limited.

4.2 Posology and method of administration

Having harmonised the indications, the CHMP also harmonised recommendations on the doses and recommendations for special populations.

4.3 Contra-indications

The CHMP agreed to include the following contraindications in the product information: hypersensitivity (allergy) to felodipine or to any other ingredients; pregnancy; decompensated heart failure (worsening of symptoms in patients with heart problems); acute myocardial infarction (heart attack); unstable angina pectoris (a type of chest pain that happens suddenly, even at rest or asleep, and which may lead to a heart attack), and certain types of heart valve and bloodflow obstructions.

Other changes

The CHMP also harmonised other sections of the SmPC, including sections 4.4 (special warnings and precautions for use), 4.6 (fertility, pregnancy and lactation) and 4.8 (side effects). The labelling and package leaflet were also revised in line with the changes to the SmPC.

The amended information to doctors and patients is available here.

The European Commission issued an EU-wide legally binding decision to implement these changes on 16 December 2014.