5 October 2010
EMA/CHMP/405853/2010 rev.1
EMEA/H/A-29/1272

Questions and answers on Fortipan Combi D and associated names (risedronate sodium 35 mg tablets / calcium plus colecalciferol 1000 mg/880 IU effervescent granules)

Outcome of a procedure under Article 29 of Directive 2001/83/EC as amended

The European Medicines Agency has completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Fortipan Combi D. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Fortipan Combi D outweigh its risks, and that the marketing authorisation granted in Sweden can be recognised in Italy.

What is Fortipan Combi D?

Fortipan Combi D is a medicine that contains three active substances, risedronate sodium, calcium carbonate and colecalciferol (vitamin D_3). It consists of tablets containing 35 mg risedronate sodium, together with sachets of effervescent granules containing 1000 mg calcium as calcium carbonate and 880 IU colecalciferol).

Fortipan Combi D is used for the treatment of osteoporosis (a disease that makes bones fragile) in women who have been through the menopause. It is used to reduce the risk of fractures in the hip and the spine. The active substance in the tablets, risedronate sodium, is a bisphosphonate. It stops the action of the osteoclasts, the cells that are involved in breaking down the bone tissue. Blocking the action of these cells leads to less bone loss. The active substances in the effervescent granules provide calcium and vitamin D, which are needed for normal bone formation.

Why was Fortipan Combi D reviewed?

Warner Chilcott UK Ltd submitted Fortipan Combi D for mutual recognition on the basis of the initial authorisation granted by Sweden on 3 October 2006. The company wanted the authorisation to be recognised in Italy (the 'concerned Member State').

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However, the Member States were not able to reach an agreement and the Swedish medicines regulatory agency referred the matter to the CHMP for arbitration on 29 April 2010.

The grounds for the referral were concerns over the evidence provided on the efficacy of this combination medicine, the validity of claims that this way of combining active substances would bring a benefit to patients compared with the individual active substances, and the validity of claims that the medicine improved compliance (the ability of patients to stick to their treatment).

What are the conclusions of the CHMP?

Based on evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that the benefits of Fortipan Combi D outweigh its risks, and therefore that the marketing authorisation for Fortipan Combi D should be granted in the concerned Member State.

The European Commission issued a decision on 5 October 2010.

Rapporteur:	Kristina Dunder (Sweden)
Co-rapporteur:	Daniela Melchiorri (Italy)
Procedure start date:	20 May 2010
Opinion date:	24 June 2010