EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Questions and answers

Withdrawal of the marketing authorisation application for Alendronic Acid/Colecalciferol Mylan (alendronic acid and colecalciferol)

On 27 May 2016, Mylan SAS officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Alendronic Acid/Colecalciferol Mylan, for the treatment of postmenopausal osteoporosis in women at risk of vitamin D deficiency.

What is Alendronic Acid/Colecalciferol Mylan?

Alendronic Acid/Colecalciferol Mylan is a medicine that contains two active substances: alendronic acid and colecalciferol. It was to be available as tablets.

Alendronic Acid/Colecalciferol Mylan was developed as a 'generic medicine'. This means that Alendronic Acid/Colecalciferol Mylan was intended to be similar to a 'reference medicine' already authorised in the European Union called Fosavance. For more information on generic medicines, see the question-and-answer document here.

What was Alendronic Acid/Colecalciferol Mylan expected to be used for?

Alendronic Acid/Colecalciferol Mylan was to be used to treat osteoporosis (a disease that makes bones fragile) in women who have been through the menopause and are at risk of insufficient vitamin-D levels. It was expected to reduce the risk of fractures (broken bones) in the spine and the hip.

How is Alendronic Acid/Colecalciferol Mylan expected to work?

Alendronic Acid/Colecalciferol Mylan is expected to work in the same way as the reference medicine, Fosavance. Alendronic acid reduces the loss of bone tissue and colecalciferol, also known as vitamin D_3, increases the absorption of calcium and formation of bone.

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What did the company present to support its application?

Because Alendronic Acid/Colecalciferol Mylan is a generic medicine, the company had presented results of a study to determine that Alendronic Acid/Colecalciferol Mylan is bioequivalent to the reference medicine, Fosavance. Two medicines are bioequivalent when they produce the same levels of the active substances in the body.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the initial documentation provided by the company and formulated a list of questions. The company had not yet responded to the questions at the time of the withdrawal.

What was the recommendation of the CHMP at that time?

Based on the review of the data, at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Alendronic Acid/Colecalciferol Mylan could not have been approved for the treatment of postmenopausal osteoporosis in women at risk of vitamin D insufficiency. The CHMP was concerned that there was uncertainty about how the bioequivalence study was conducted. The CHMP also considered that data from the study do not convincingly establish that Alendronic Acid/Colecalciferol Mylan is sufficiently similar to the reference medicine, Fosavance.

Therefore, at the time of the withdrawal, the CHMP was of the opinion that the medicine could not have been approved based on the data presented by the company.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that the time required to generate the supporting data makes this product unviable.

The withdrawal letter is available here.

What consequences does this withdrawal have for patients in clinical trials or compassionate use programmes?

The company informed the CHMP that this withdrawal has no consequences for patients. There are no ongoing clinical trials or compassionate use programmes.