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Questions and answers

Withdrawal of the marketing authorisation application for Corluxin (mifepristone)

On 23 March 2015, FGK Representative Service GmbH officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Corluxin, intended for the treatment of Cushing's syndrome.

What is Corluxin?

Corluxin is a medicine containing the active substance mifepristone. It was to be available as 300 mg tablets.

What was Corluxin expected to be used for?

Corluxin was to be used to treat Cushing's syndrome in patients who cannot have surgery or for whom surgery has failed.

Cushing's syndrome is a disease characterised by an excess production of the hormone cortisol by the adrenal glands, two glands situated above the kidneys. Patients with Cushing's syndrome can have 'central' weight gain (affecting the face and torso but not the limbs), growth of fat above the collar bone and the back of the neck, a roundish face, easy bruising, excessive growth of coarse hair on the face, weakening of the muscles and bones, depression, diabetes and high blood pressure.

How is Corluxin expected to work?

The active substance in Corluxin, mifepristone, is known to block receptors for cortisol known as glucocorticoid (GR-II) receptors. By blocking these receptors, mifepristone is expected to reduce the effects of the excess cortisol circulating in the body, thereby alleviating the symptoms of the disease.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

What did the company present to support its application?

The applicant submitted data from a main study involving 50 patients with Cushing's syndrome who had diabetes and/or high blood pressure, two common features of the condition. The study looked at improvements in blood sugar levels and blood pressure following 24 weeks of Corluxin treatment. Corluxin was not compared with any other medicine.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the documentation provided by the company and formulated lists of questions.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

What was the recommendation of the CHMP at that time?

At the time of the withdrawal, the CHMP was of the provisional opinion that Corluxin could not be approved for use in the broad indication the company applied for, which was the "treatment of adult patients with endogenous Cushing's syndrome for whom surgery is not an option or for whom surgery has failed."

The CHMP had concerns related to the manufacture of the medicine, including the control of impurities and the testing of the finished product. The CHMP also had concerns about the main study, citing, among other things, the lack of a comparator medicine.

On the whole, the evidence for effectiveness in the indication applied for was limited and there were some safety concerns with the medicine, including side effects caused by the reduced activity of circulating cortisol, fluid and mineral disturbances (particularly reduced potassium levels in blood and increased blood pressure in some patients) and thickening of the womb in some female patients. Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Corluxin in the proposed indication did not outweigh its risks.

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 withdrawal was due to strategic business reasons.

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, at the time of the withdrawal, there were no ongoing clinical trials or compassionate use programmes for Corluxin.