



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Withdrawal of the marketing authorisation application for Balimek (binimetinib)

On 4 January 2018, Pierre Fabre Médicament officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wished to withdraw its application for a marketing authorisation for Balimek, for the treatment of melanoma.

What is Balimek?

Balimek is a medicine that contains the active substance binimetinib. It was to be available as tablets to be taken by mouth.

What was Balimek expected to be used for?

Balimek was expected to be used for treating melanoma (a type of skin cancer) that had spread or could not be removed by surgery. It was to be used in patients who had a specific genetic mutation (change) called NRAS Q61 mutation.

How does Balimek work?

The active substance in Balimek, binimetinib, blocks proteins called MEK1 and MEK2. These proteins encourage the growth of new cells. By blocking the MEK proteins, Balimek is expected to slow down the growth of melanoma cells.

What did the company present to support its application?

The company presented data from one main study comparing Balimek with dacarbazine (a cancer medicine used for treating melanoma). The study involved 402 patients with advanced melanoma with the NRAS Q61 mutation that had spread or could not be removed by surgery. The main measure of effectiveness was how long patients lived without their disease getting worse.



How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the documentation provided by the company and formulated lists of questions.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 responded to the last round of questions at the time of the withdrawal.

What was the recommendation of the CHMP at that time?

Based on the data reviewed, at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Balimek could not have been approved for the treatment of advanced melanoma in patients with the NRAS Q61 mutation.

The CHMP noted that patients treated with Balimek lived slightly longer without their disease getting worse compared with those receiving dacarbazine. Considering this, along with data on the time patients lived overall and their quality of life, the CHMP considered that Balimek's effectiveness was questionable. Moreover, the CHMP was concerned that Balimek was linked to worse side effects than dacarbazine.

The Committee also considered that although no medicine is approved specifically to treat patients with the NRAS Q61 mutation, there are effective treatments for melanoma in general. The evidence provided was insufficient to show that Balimek fulfils an unmet medical need.

Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Balimek 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 the application, the company stated that the withdrawal is based on CHMP's opinion that the data supplied did not provide sufficient evidence to conclude that the medicine's benefits outweigh its risks.

The withdrawal letter is available [here](#).

What consequences does this withdrawal have for patients in clinical trials?

The company informed the CHMP that there are no consequences for patients currently included in clinical trials using Balimek.

If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.