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Questions and answers

Withdrawal of the application for a change to the marketing authorisation for Teysuno (tegafur/gimeracil/oteracil)

On 6 January 2015, Nordic Group BV officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a change to the indication for Teysuno. The change concerned extending the use of Teysuno to treat advanced gastric cancer in combination with platinum-based cancer medicines other than cisplatin.

What is Teysuno?

Teysuno is a cancer medicine that is used to treat adults with advanced gastric (stomach) cancer. It is used in combination with cisplatin (a platinum-based cancer medicine).

Teysuno contains the active substances tegafur, gimeracil and oteracil. It is available as capsules.

Teysuno has been authorised in the EU since March 2011.

What was Teysuno expected to be used for?

Teysuno was also expected to be used in combination with platinum-based cancer medicines other than cisplatin, such as oxaliplatin.

How is Teysuno expected to work?

The main active substance in Teysuno, tegafur, is a cytotoxic medicine (a medicine that kills cells that are dividing, such as cancer cells) that belongs to the 'anti-metabolites' group. Tegafur is a 'prodrug' that is converted in the body to another medicine called 5-fluorouracil (5-FU). 5-FU is similar to pyrimidine, a substance found in the genetic material of cells (DNA and RNA). In the body, 5-FU takes

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

the place of pyrimidine and interferes with the enzymes involved in making new DNA. As a result, it prevents the growth of cancer cells and eventually kills them.

The two other active substances in Teysuno allow tegafur to be effective at lower doses and with fewer side effects: gimeracil by preventing the breakdown of 5-FU, and oteracil by reducing the activity of 5-FU in normal, non-cancerous tissue in the gut.

What did the company present to support its application?

The company presented data from two studies involving a total of 43 patients with advanced gastric cancer or other tumours, in which Teysuno was used in combination with oxaliplatin and other cancer medicines. Data from published studies on the use of Teysuno in combination with platinum-based medicines were also provided.

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 a list of questions. After the CHMP had assessed the company's responses to the questions, there were still some unresolved issues.

What was the recommendation of the CHMP at that time?

Based on the review of the data and the company's response to the CHMP list of questions, at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Teysuno could not have been approved for the treatment of advanced gastric cancer in combination with platinum-based medicines other than cisplatin. The data provided were too limited to allow a benefit-risk evaluation of Teysuno in combination with other platinum-based medicines in patients with advanced gastric cancer. In particular very limited data were provided on the combination of Teysuno with oxaliplatin and no data were provided on the use with carboplatin.

Therefore, at the time of the withdrawal, the CHMP was of the opinion that the data provided were too scarce to allow adequate evaluation of the benefits and risks of Teysuno in combination with platinum-based medicines other than cisplatin in patients with advanced gastric cancer.

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 it withdrew the application because, in its preliminary assessment report, the CHMP considered that the data provided were insufficient to conclude that the benefits outweigh the risks when Teysuno is used in combination with other platinum-based cancer medicines.

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 there are no consequences for patients in clinical trials or compassionate use programmes.

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

What is happening with Teysuno for the treatment of patients with advanced gastric cancer in combination with cisplatin?

There are no consequences on the use of Teysuno in its authorised indication.

The full European Public Assessment Report for Teysuno can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.