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Questions and answers

Withdrawal of the marketing authorisation application for Comfyde (carisbamate)

Summary of the application at the time of withdrawal

On 15 January 2010, Janssen-Cilag International NV officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Comfyde, for use in the treatment of partial-onset seizures in patients with epilepsy.

What is Comfyde?

Comfyde is a medicine that contains the active substance carisbamate. It was to be available as tablets.

What was Comfyde expected to be used for?

Comfyde was expected to be used as an add-on to existing treatments for partial-onset seizures (fits) with or without secondary generalisation in patients with epilepsy. This is a type of epilepsy where too much electrical activity in one side of the brain causes symptoms such as sudden, jerky movements of one part of the body, distorted hearing, sense of smell or vision, numbness or a sudden sense of fear. Secondary generalisation occurs when the overactivity later reaches the whole brain. Comfyde was expected to be used to treat patients aged 16 years and above.

How is Comfyde expected to work?

The active substance in Comfyde, carisbamate, is an anti-epileptic medicine. The exact way in which carisbamate works in the body is not known, but some of its activity might be explained by the blocking of sodium channels (pores on the surface of nerve cells) that allow electrical impulses to be transmitted between nerve cells. By reducing the activity of sodium channels and through its other possible actions, carisbamate was expected to prevent abnormal electrical activity spreading through the brain, reducing the chance of an epileptic fit happening.

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What documentation did the company present to support its application?

The effects of Comfyde were first tested in experimental models before being studied in humans.

The company also presented data from three main studies involving 1,664 patients with partial-onset seizures who were already treated with up to three other anti-epileptic medicines. The patients added either Comfyde or placebo (a dummy treatment) to their existing treatment. The main measures of effectiveness were the reduction in the average number of seizures every month and the number of patients who had their monthly number of seizures reduced by at least a half.

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

The application was withdrawn before 'day 120'. This means that the CHMP was still evaluating the initial documentation provided by the company.

What was the recommendation of the CHMP at that time?

As the CHMP was evaluating the initial documentation provided by the company, it had not yet made any recommendations.

What were the reasons given by the company to withdraw the application?

The letter from the company notifying the Agency of the withdrawal of the application is available here.

What are the consequences for patients in clinical trials or compassionate use programmes with Comfyde?

The company has informed the CHMP that patients in epilepsy clinical trials will have their Comfyde treatment discontinued gradually. As this is being done, other medicines the patients are receiving for epilepsy may be adjusted as needed.