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Withdrawal of application for the marketing authorisation of Vivjoa (oteseconazole)

On 24 August 2023 Gedeon Richter plc withdrew its application for a marketing authorisation of Vivjoa for the treatment and prevention of vulvovaginal candidiasis (thrush, a fungal infection of the female genital area caused by *Candida*).

What is Vivjoa and what was it intended to be used for?

Vivjoa was developed as a medicine for the treatment and prevention of vulvovaginal candidiasis in women who have recurrent infections (i.e. three or more infections with symptoms in a year). It was to be used in women who cannot become pregnant.

Vivjoa contains the active substance oteseconazole and was to be available as capsules to be taken by mouth.

How does Vivjoa work?

The active substance in Vivjoa, oteseconazole, works by blocking CYP51, an enzyme produced by the fungus that causes candidiasis (*Candida*) and which is involved in its development. By blocking CYP51, oteseconazole is expected to stop the growth of the fungus.

What did the company present to support its application?

The company presented the results from three main studies. The first two studies were similar; they were each carried out in around 330 women with recurrent vulvovaginal candidiasis who were experiencing an acute episode of vulvovaginal candidiasis at the start of the study. During the first week, all women received 3 doses of fluconazole, another antifungal medicine. After 14 days, women whose acute episode of vulvovaginal candidiasis had resolved then received either Vivjoa or placebo (a dummy treatment) for 12 weeks. The main measure of effectiveness was the number of women who had one or more episode of acute vulvovaginal candidiasis during the 48 weeks after starting Vivjoa or placebo.

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The third study involved 219 women with an episode of acute vulvovaginal candidiasis. The first week, they received either 2 doses of Vivjoa or 3 doses of fluconazole. After 14 days, women whose acute episode of vulvovaginal candidiasis had resolved then received either Vivjoa (if they initially received Vivjoa) or placebo (if they initially received fluconazole) for 11 weeks. The main measure of effectiveness was the number of people who had one or more episodes of acute vulvovaginal candidiasis during the 50 weeks after starting Vivjoa or fluconazole. The study also looked at the number of women whose acute vulvovaginal candidiasis at the start of the study resolved in the first 14 days.

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

The application was withdrawn after that the European Medicines Agency had evaluated the information from the company and prepared questions for the company. The company had not responded to the last round of questions at the time of the withdrawal.

What did the Agency recommend at that time?

Based on the review of the data and the company's response, at the time of the withdrawal, the Agency's provisional opinion was that Vivjoa could not have been authorised for the treatment and prevention of recurrent vulvovaginal candidiasis.

The Agency had concerns about the quality of the active substance as the manufacturing process did not include adequate controls to check the levels of impurities called azoxy impurities. In terms of effectiveness, the Agency considered that there was no convincing evidence that Vivjoa was effective at treating acute episodes of vulvovaginal candidiasis. Finally, the Agency did not agree with the company's proposal to prevent the use of Vivjoa in women who cannot have children but plan to conceive via assisted reproduction within 2 years and 8 months after starting treatment with Vivjoa.

Therefore, at the time of the withdrawal, the Agency's opinion was that the company had not fully addressed its concerns and the benefit of Vivjoa in the treatment of acute episodes of vulvovaginal candidiasis could not be established.

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 its application for commercial reason.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no ongoing clinical trials in the EU.

If you were involved in a clinical trial and have questions about your treatment, speak with your clinical trial doctor.