

Date: 24. August 2023

Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of the Marketing Authorisation Application for Vivjoa (oteseconazole) 150 mg hard capsules (EMA/H/C/005682)

Dear Dr. Harald Enzmann,

I would like to inform you that, at this point of time, Gedeon Richter Plc. has taken the decision to withdraw the application for Marketing Authorisation of Vivjoa (oteseconazole) 150 mg hard capsules. Vivjoa was intended to be used for the treatment of a new symptomatic episode in adult female patients who have recurrent vulvovaginal candidiasis (RVVC) and prevention of acute vulvovaginal candidiasis in adult female patients who have a history of RVVC.

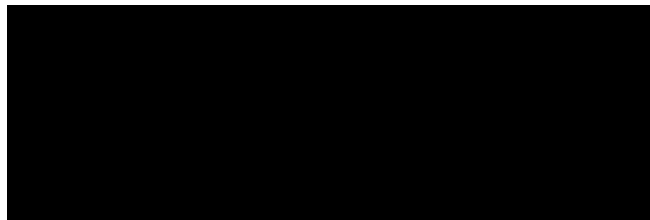
This withdrawal is based on business reasons.

We reserve the right to make further applications for this Marketing Authorisation at a future time.

Gedeon Richter would like to sincerely thank the (Co-)Rapporteurs, EMA, PRAC and the CHMP members for the time dedicated for reviewing this application as well as for the support provided during the pre-submission phase and throughout the procedure.

I agree for this letter to be published on the EMA website.

Yours sincerely,



Gedeon Richter Plc.
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Hungary

Chemical Works of Gedeon Richter Plc.