



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): fezolinetant

Procedure No. PSUSA/00000231/202505; EMA/PSUR/0000288230

Period covered by the PSUR:
11/11/2023 To: 11/05/2024



Scientific conclusions and grounds for variation to the terms of the marketing authorisations

In view of available data from clinical trials and information provided in the present PSUSA, the PRAC recommended to remove information about incidence rates of ALT/AST elevations calculated from pooled data of clinical trials in SmPC Section 4.8, due to the heterogeneity of clinical studies on fezolinetant and since it was decided that such information does not provide relevant additional value for HCPs. There is also a consequential removal of the asterisk in the respective cell of the Adverse reactions table.

The PRAC concluded that the product information of products containing fezolinetant should be amended accordingly.