Jevtana

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IB /	C.I HUMAN AND VETERINARY MEDICINAL	30/09/2025		SmPC and PL	

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

EMA/VR/0000295586	PRODUCTS - C.I.z Other variation - Accepted C.I.z (Type IB) – To update Section 4.2 of the SmPC by removing ranitidine as an example of an H2 antagonist, and to revise Sections 2 and 4.4 of the SmPC, as well as Section 2 of the PL, to include information on the excipient polysorbate 80, based on the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'. In addition, the MAH took the opportunity to implement editorial changes to the PL by removing the local representative for UK (NI) in alignment with the QRD template and updated the name of the local representative for IS.				
Variation type IA_IN / EMA/VR/0000274737	B.III.2.a Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.a.1 Active substance - Accepted	23/05/2025	N/A		