Fexinidazole Winthrop

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 II / EMA/VR/0000287639	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics,	09/10/2025	N/A	SmPC and PL	Sections 4.2 and 6.6 of the SmPC were updated to modify administration instructions to be followed to allow patients who are unable to take the

[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).

	Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.2, and 6.6 of the SmPC in order to modify administration instructions following to allow patients who are unable to take the fexinidazole tablets whole, to either crush the tablets or dissolve them in water.				fexinidazole tablets whole, to either crush the tablets or dissolve them in water. Section 3 of the PL was amended accordingly. For more information, please refer to the Summary of Product Characteristics.