Ypozane

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued / amended on	Product Information affected[2]	Summary[3]
IAIN/0005	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	27/08/2021		PL	The Agency accepted the variation to update the list of local representatives.
IG/0808	C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities	29/05/2019	n/a		n/a
IG/0984	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	26/10/2018	25/10/2019	PL	The Agency accepted the variation to update the local representatives in the package leaflet.
IG/0724	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	21/12/2016	09/01/2018	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
R/0001	Renewal of the marketing authorisation.	13/10/2011	19/12/2011		The European Commission renewed the marketing authorisation for Ypozane.

[1] Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.
[2] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).
[3] Since October 2019 summary information is no longer published for variations that do not impact upon the product information

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