Duloxetine Zentiva

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, please 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.2 Change(s) in the Summary of Product	19/11/2024		SmPC and PL	Update of section 4.4 of the SmPC to amend 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).

EMA/VR/0000226488	Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted To update section 4.4 of the SmPC to amend the information about serotoninergic syndrome and to add information about the neuroleptic malignant syndrome and to update of section 4.8 the SmPC to include stress cardiomyopathy (Takotsubo cardiomyopathy) under SOC "Cardiac disorders" with frequency not known. In addition the MAH has taken this opportunity to update the release address in Annex II to be in line with SPOR and also to amend the details of the local representative in Spain and to remove the local representative for UK (NI) in line with QRD version 10.4.				information about serotoninergic syndrome and to add information about the neuroleptic malignant syndrome and to update of section 4.8 the SmPC to include stress cardiomyopathy (Takotsubo cardiomyopathy) under SOC "Cardiac disorders" with frequency not known. In addition the MAH has taken this opportunity to update the release address in Annex II to be in line with SPOR and also to amend the details of the local representative in Spain and to remove the local representative for UK (NI) in line with QRD version 10.4.
Article 61(3) / EMA/N/0000170584	- - Accepted Update of the package leaflet with revised contact details of local representatives.	13/03/2024		PL	
Variation type IB / EMA/VR/0000166577	This was an application for a group of variations. B.III.1.a European Pharmacopoeial	15/02/2024	N/A		

	Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted				