EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Bovalto Ibraxion

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion / Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
IAIN/0016	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	10/08/2016		SPC, Labelling and PL	The European Medicines Agency accepted the variation to change the name of the medicinal product from Ibraxion to Bovalto Ibraxion
WS/0818	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.III.1.b.2 - Submission of a new/updated CP or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	08/10/2015	n/a		The European Medicines Agency accepted a variation to add two new TSE certificates of suitability from EDQM.
WS/0774	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	10/09/2015	n/a		The European Medicines Agency accepted the variation to make changes in the manufacturing process of the active substance.

[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] A CD is issued for procedures that affect the terms of the marketing authorisation (e.g. SPC, Annex II, Labelling, PL). The CD is issued within 2 months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within 1 year for other procedures.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

WS/0546	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	11/09/2014	n/a		The European Medicines Agency approved the variation relating to Foetal Bovine Serum.
IB/0012	B.III.1.b.z - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - European Pharmacopoeial TSE Certificate of suitability - Other variation	05/10/2012	n/a		The European Medicines Agency accepted a variation related to a new supplier of a starting material
R/0011	Renewal of the marketing authorisation.	09/12/2009	23/03/2010	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Ibraxion.
II/0010	II - Other quality changes	12/03/2008	14/03/2008		The European Commission approved a type II variation regarding removal of routine safety batch testing.
IB/0009	1B-25-a-2 Change to comply with Eu. Ph. or with the national pharmacopoeia of a Member State	08/02/2008	08/02/2008		The European Medicines Agency accepted a type IB variation regarding the compliance of an excipient with the European Pharmacopoeia.
R/0008	Renewal of the marketing authorisation.	12/01/2005	27/04/2005	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Ibraxion.
I/0007	03_Change in the name and/or address of the marketing authorisation holder	12/08/2003	22/09/2003	SPC, Labelling and PL	The European Medicines Agency accepted a type I variation to change the address of the marketing authorisation holder.
I/0006	01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	12/08/2003	22/09/2003	SPC, Labelling and PL	The European Medicines Agency accepted a type I variation to change the batch release site.
I/0005	11b_Change in supplier of an intermediate compound used in manufacture of the active substance	15/04/2003	15/04/2003		The European Medicines Agency accepted a type I variation to include additional bovine serum suppliers.
II/0003	II - Other quality changes	13/11/2002	14/02/2003	SPC, Labelling and PL	The European Commission approved a type II variation to modify the warning relating to the mineral oil content of the product.
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/10/2002	14/11/2002	PL	A notification of a change in the local representatives was sent to the European Commission.
II/0002	II - Other quality changes	15/05/2002	03/06/2002		The European Commission approved a type II variation relating to the use of material of ruminant origin in Ibraxion and the demonstration of compliance with the CPMP/CVMP "Note for Guidance on minimising the risk of transmitting spongiform encephalopathy agents via human and veterinary medicinal products".

I/0001	01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	12/07/2000	12/07/2000		The European Medicines Agency accepted a type I variation to change the manufacturing site for part of the manufacturing process.