EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Rivastigmine Teva

Procedural steps taken and scientific information after the authorisation

No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
IB/0008/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH	31/08/2011	n/a	SPC, PL	Update sections 4.3 and 4.4 of Nimvastid SmPC to change the contraindication for patients with severe hepatic impairment into a warning. Section 4.4 of the SmPC is also revised to reflect that patients with clinically significant renal or hepatic impairment might experience more adverse reactions. Section 4.2 is amended accordingly. In addition, minor linguistic amendments have been introduced in the SmPC. The Package Leaflet of has been revised based on the results of a user testing of the reference product. In addition, section 4.8 of the SmPC has been amended to include new adverse reactions: dehydration, hepatitis, aggression, restlessness, sick sinus syndromes and anxiety. The whole section 4.8 has been revised according to the current MedDRA terminology. Furthermore, Section 4.4 of the SmPC has also been amended to include that gastrointestinal disorders may occur when in patients treated with rivastigmine and to include a warning for patients with low body weight. The Package Leaflet has been amended to reflect those changes, and the local representative section has also been updated.

[1] Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.
[2] No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
IA/0007/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer of the manufacturer responsible for batch release, A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release)	15/08/2011	n/a	Annex II, PL	
IB/0006	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH	04/06/2010	n/a	SPC, PL	Further to the assessment of PSUR 16 for the reference medicinal product, section 4.8 of the SPC of the patch formulation has been updated to include "hallucinations", "tachycardia", "atrioventricular block", "atrial fibrillation", "hypertension", "pancreatitis", "worsening of PD", "falls" and "seizures". Information on misuse and dosing errors has been added to section 4.9 of the SPC for transdermal patches, and cross referred with section 4.2. For all formulations, updated information on skin reactions has been included in section 4.8 of the SPC. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to include minor amendments throughout the annexes, to update the local representatives and to update the Product information in line with current QRD requirements.
IA/0005	07_a_Replacement/add. of manufacturing site: Secondary packaging site	19/10/2009	n/a		
IA/0003	32_a_Change in batch size of the finished product - up to 10-fold	12/10/2009	n/a		
IA/0002	31_a_Change to in-process tests/limits during manufacture - tightening of in-process limits	12/10/2009	n/a		
IA/0004	32_b_Change in batch size of the finished product - downscaling down to 10-fold	12/10/2009	n/a		
IA/0001	08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	17/06/2009	n/a	Annex II, PL	