EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Sildenafil Actavis

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
IG/1612	A.1 - Administrative change - Change in the name and/or address of the MAH	31/05/2023		SmPC, Labelling and PL	
IB/0023	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	27/06/2022		SmPC and PL	To update section 4.5 of the SmPC to add a warning about the increase in hypotension observed with concomitant use

[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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

					of sildenafil and sacubitril/valsartan.
IAIN/0022/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/importer responsible for batch release A.7 - Administrative change - Deletion of manufacturing sites	12/03/2021	23/07/2021	Annex II and PL	
IA/0021/G	This was an application for a group of variations. B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	11/03/2021	n/a		
IB/0020	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	05/08/2020	23/07/2021	SmPC, Annex II, Labelling and PL	
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/11/2018	23/07/2021	PL	

N/0018	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/04/2018	23/07/2021	PL	
IB/0017/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	06/06/2016	22/05/2017	SmPC, Labelling and PL	
IA/0016	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	23/05/2016	n/a		
IA/0015	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	23/05/2016	n/a		
IB/0014	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	22/12/2015	25/01/2016	SmPC, Labelling and	

	assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH			PL	
IB/0013/G	This was an application for a group of variations. B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	08/06/2015	n/a		
IAIN/0012	B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	29/05/2015	n/a		
R/0010	Renewal of the marketing authorisation.	24/07/2014	04/09/2014	SmPC and PL	Based on the CHMP review of the available information and on the basis of a re-evaluation of the benefit risk balance, the CHMP is of the opinion that the quality, safety and efficacy of sildenafil actavis continues to be adequately and sufficiently demonstrated and therefore considered that the benefit risk profile of sildenafil actavis continues to be favourable in the treatment of adult men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for sildenafil actavis to be effective, sexual stimulation is required. The CHMP recommends that

					the renewal be granted with unlimited validity.
IAIN/0011	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	25/04/2014	04/09/2014	Annex II and PL	
IB/0009/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 is required to be submitted by the MAH 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 is required to be submitted by the MAH	04/11/2013	03/03/2014	SmPC, Labelling and PL	1. Harmonisation of the PI in line with the Originator product and update to the latest QRD template vs.9. 2. Update of Section 4.4 of the SmPC to revise the information on acute NAION based on new data coming from the clinical study A1481259 according to the Originator. The package leaflet was amended accordingly.
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/10/2013	03/03/2014	PL	Update of the local representatives contact details and inclusion of an additional local representative of the MAH for the new Member State, Croatia.
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	20/03/2013	03/03/2014	SmPC, Annex II and PL	Implementation of changes approved in the reference product - update of section 4.8 to add 'Penile haemorrhage, Haematospermia, and Haematuria' with an uncommon frequency and deletion of the footnote referring to ear disorders as requested by CHMP. The Package Leaflet was updated accordingly. The MAH also took the opportunity to make minor linguistic amendments in line with the

					reference product and to update Annex II according to the latest QRD template.
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/01/2013	03/03/2014	PL	Update of the list of local representatives contact details in the package leaflet.
IB/0003	B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	23/08/2012	n/a		
IB/0002	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	24/03/2011	n/a	SmPC, Annex II and PL	Addition of the adverse drug reactions Stevens Johnsons Syndrome (SJS) AND Toxic Epidermal Necrolysis with unknown frequency in the SmPCs and PLs. The MAH also updated the EMA address in the SmPCs and in the PLs and deleted the DDPS version number in Annex IIB. These changes were made to bring this product information in line with the Originator product information.
IA/0001	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	20/10/2010	n/a		