Kentera

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
IB/0067/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.e.1.a.2 - Change in immediate packaging of the	02/10/2024		SmPC and PL	

[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).

	finished product - Qualitative and quantitative composition - Semi-solid and non-sterile liquid pharmaceutical forms				
PSUSA/2253/202207	Periodic Safety Update EU Single assessment - oxybutynin	30/03/2023	26/05/2023	SmPC and PL	Please refer to Kentera-EMEA/H/C/PSUSA/00002253/202207 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IB/0065	B.II.z - Quality change - Finished product - Other variation	05/10/2022	n/a		
IAIN/0064	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/06/2022	n/a		
IB/0062	C.I.7.a - Deletion of - a pharmaceutical form	11/11/2021	09/11/2022	SmPC, Labelling and PL	
IA/0063	A.7 - Administrative change - Deletion of manufacturing sites	06/10/2021	n/a		
N/0061	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/07/2021	09/11/2022	PL	
IA/0060	A.7 - Administrative change - Deletion of manufacturing sites	19/02/2021	n/a		
II/0059	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	04/02/2021	n/a		

IB/0058/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	12/08/2020	n/a		
IAIN/0057/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	31/03/2020	09/03/2021	Annex II and PL	
IB/0053	B.II.a.3.b.6 - Changes in the composition (excipients) of the finished product - Other excipients - Replacement of a single excipient with a comparable excipient with the same functional characteristics and at a similar level	16/01/2020	n/a		
IB/0056	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	18/12/2019	n/a		

IA/0055	B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material	03/12/2019	n/a		
N/0054	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/11/2019	09/03/2021	PL	
IB/0051/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits	16/07/2019	n/a		
IAIN/0050/G	This was an application for a group of variations. B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	20/12/2018	14/11/2019	Annex II and PL	
T/0049	Transfer of Marketing Authorisation	06/11/2018	22/11/2018	SmPC, Labelling and PL	

II/0047	B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a manufacturer of the AS supported by an ASMF	15/11/2018	n/a		
IAIN/0048/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	09/08/2018	n/a		
IB/0046	B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	26/06/2018	n/a		
IAIN/0045	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	03/05/2018	22/11/2018	Annex II and PL	
PSUSA/2253/201707	Periodic Safety Update EU Single assessment - oxybutynin	08/03/2018	n/a		PRAC Recommendation - maintenance

IA/0044/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient 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	23/02/2018	n/a		
IA/0042	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	20/07/2017	n/a		
II/0041	Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to implement the adopted wording from the final PRAC recommendation on the signal on psychiatric disorders. Updates to the agreed PRAC wording are also made in sections 4.2 and 4.4 to further clarify the dose adjustment in the elderly population and in section 4.8 to clarify the text on adverse reactions considered associated with anticholinergic therapy. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the SmPC (Annex I), Labelling (Annexe IIIA) and Package leaflet (Annexe IIIB) in accordance with EDQM standards terms.	10/11/2016	16/12/2016	SmPC, Labelling and PL	Based on clinical trial experience no dose adjustment is considered necessary in the elderly population. Nonetheless Kentera should be used with caution in elderly patients, who may be more sensitive to the effects of centrally acting anticholinergics and exhibit differences in pharmacokinetics (see section 4.4 of the SmPC). In total 496 patients were exposed to Kentera in the randomised, double-blind, placebo-controlled 12-week and the 14-week safety extension studies. Of these 188 patients (38%) were 65 years of age and older and exhibited no overall differences in safety or effectiveness compared to younger patients. Thus based on current clinical evidence no need for dose adjustment in elderly patients is considered necessary. Psychiatric and central nervous system (CNS)

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				anticholinergic events like sleep disorders (e.g. insomnia) and cognitive disorders have been associated with oxybutynin use, especially in elderly patients. Caution should be exercised when oxybutynin is administrated concomitantly with other anticholinergic medicines (see also section 4.5 of the SmPC). If a patient experiences such events, drug discontinuation should be considered. Other psychiatric events implying an anticholinergic mechanism have been reported during post-marketing use (see section 4.8 of the SmPC). Section 4.8 was updated to add that adverse reactions considered associated with anticholinergic therapy in general or observed with oral administration of oxybutynin, but as of yet not with Kentera in clinical trials or post-marketing, are: anorexia, vomiting, reflux oesophagitis, decreased sweating, heat stroke, decreased lacrimation, mydriasis, tachycardia, arrhythmia, nightmares, restlessness, convulsion, intraocular hypertension and induction of glaucoma, paranoia, photosensitivity, erectile dysfunction. In the paediatric population, the safety and efficacy of Kentera has not been established. Kentera is not recommended for use in the paediatric population. Currently available data are described in section 4.8 but no recommendation on a posology can be made. Section 4.8 of the SmPC was also updated to bring it in line with the SmPC guidance presenting the adverse event as tabulated list.
IA/0039/G	This was an application for a group of variations. B.II.b.5.b - Change to in-process tests or limits	23/07/2015	n/a		

	applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier				
IB/0038	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	19/12/2014	16/12/2015	SmPC and PL	
N/0037	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/07/2014	16/12/2015	Labelling and PL	
IB/0036	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	23/05/2014	n/a		
IAIN/0035	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	28/01/2014	n/a		
N/0034	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/12/2013	16/12/2015	Labelling and PL	
IB/0033	B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF	18/04/2013	n/a		

IB/0032/G	This was an application for a group of variations. B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	15/03/2013	n/a		
IB/0031	B.II.e.1.a.2 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Semi-solid and non-sterile liquid pharmaceutical forms	15/02/2013	n/a		
IA/0030	B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place	29/11/2012	n/a		
IA/0029	B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	09/10/2012	n/a		

IAIN/0028	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	06/09/2012	n/a		
IB/0027	C.I.8.b - Introduction of a new Pharmacovigilance system - which has been assessed by the relevant NCA/EMA for another product of the same MAH	24/04/2012	n/a		
IB/0026/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS A.7 - Administrative change - Deletion of manufacturing sites B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an	21/03/2012	n/a		

	ASMF				
IB/0024	B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	11/01/2012	n/a		
N/0025	Update of the local representatives contact details for Austria and Germany. The MAH also took the opportunity to correct typographical errors in the Italian and Dutch package leaflets. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/12/2011	16/12/2015	PL	
IB/0021/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.1.g - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter as a result of a safety or quality issue	17/11/2011	n/a		

IA/0023	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV	11/10/2011	n/a		
X/0016	Annex I_1.(a) Replacement of a chemical AS by diff. salt/ester complex/derivative, with the same therapeutic moiety Annex I_2.(d) Change or addition of a new pharmaceutical form	19/05/2011	24/08/2011	SmPC, Labelling and PL	
IA/0020	C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV	20/05/2011	n/a	Annex II	
IA/0019/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV	21/09/2010	n/a	Annex II	
N/0018	The MAH updated the contact details of the list of local representatives for the United Kingdom, Czech Republic and Slovakia and made a minor linguistic change in section 5 of the Package Leaflet in all the appropriate EU language versions. They also took the opportunity to make minor formatting changes throughout the list of local representatives.	03/09/2010	n/a	PL	

	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)				
IB/0017/G	This was an application for a group of variations. B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method	06/08/2010	n/a	SmPC	
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/12/2009	n/a	PL	
R/0014	Renewal of the marketing authorisation.	19/02/2009	30/04/2009	SmPC, Annex II, Labelling 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 this medicinal product continues to be adequately and sufficiently demonstrated and therefore considered that the benefit risk profile of Kentera continues to be favourable. The CHMP is also of the opinion that the renewal can be granted with unlimited validity.
N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	28/08/2008	n/a	PL	
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/08/2007	n/a	PL	

IA/0011	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	30/10/2006	n/a		
N/0010	The Marketing Authorisation Holder (MAH) applied for minor changes to the labelling and package leaflet texts following comments received from the EMEA on the specimen checks. The changes consisted in the inclusion in the labelling (section instructions of use) of a reference to the days when the dose should be taken. Additionally the whole list of local representatives was added to the package leaflet. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/12/2005	n/a	Labelling and PL	
IA/0009	IA_25_b_02_Change to comply with Ph. - compliance with EU Ph. update - excipient	25/08/2005	n/a	SmPC, Labelling and PL	
IA/0008	IA_08_a_Change in BR/QC testing - repl./add. of batch control/testing site	23/08/2005	n/a		
IA/0007	IA_38_a_Change in test procedure of finished product - minor change to approved test procedure	20/04/2005	n/a		
II/0005	Quality changes	17/02/2005	21/02/2005		
IB/0006	02_Change in the name of the medicinal product (either invented name of common name)	23/11/2004	n/a	SmPC, Labelling and PL	

IB/0004	IB_41_a_02_Change in pack size - change in no. of units outside range of appr. pack size	27/10/2004	27/10/2004	SmPC, Labelling and PL	
IA/0003	IA_38_a_Change in test procedure of finished product - minor change to approved test procedure	23/07/2004	n/a		