EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Cerenia

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued / amended on	Product Information affected[2]	Summary[3]
IB/0040	C.I.3.z - Change(s) in the SPC, Labelling or PL of veterinary medicinal products intended to implement the outcome of a procedure concerning PSUR: implementation of wording agreed by the competent authority that does not require additional assessment	13/08/2021		SPC and PL	The Agency accepted the variation to update section 4.6 of the SPC and section 6 of the package leaflet following assessment of the 20th PSUR.
IA/0038	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	26/03/2021	n/a		n/a
IB/0037	B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data)	21/02/2020	09/02/2021	SPC, Labelling and PL	The Agency accepted the variation to increase the in-use shelf-life after first opening of Cerenia solution for injection from 28 days to 60 days. In addition the applicant is aplying changes which have been notified under product defect notification and is making editorial changes related to the QRD template.
IB/0036/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.b.2.e - Change in test procedure for AS or starting	12/02/2020	n/a		n/a

[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] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).
[3] Since October 2019 summary information is no longer published for variations that do not impact upon the product information

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

	material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				
IB/0035/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.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold B.II.c.1.g - Change in the specification parameters and/or limits of an excipient - Where there is no monograph in the European/National Ph. for the excipient, a change in specification from in-house to a non-official/third country Ph.	31/10/2018	11/11/2019	Annex II and PL	The Agency accepted the group of variations to add an alternative manufacturer of the finished product (including also the activities: primary and secondary packaging, batch release & quality control); to process the changes in the batch size for the finished product; and to register an alternate specification for the testing of an excipient.
IG/0976	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	26/10/2018	11/11/2019	PL	The Agency accepted the variation to delete the list of local representatives from the product information.
IG/0951	C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities	05/07/2018	n/a		n/a
IG/0936	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)	13/06/2018	n/a		The Agency accepted the group of variations to make a change in the legal entity name of the manufacturing site used to manufacture the finished products.
IG/0851	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)	15/11/2017	n/a		The Agency accepted the variation to change the name of the secondary packaging site.
IB/0030	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	31/08/2017	03/08/2018	SPC and PL	The Agency accepted a variation to amend Section 4.5 of the summary of product characteristics (SPC): Special precautions to be taken by the person administering the veterinary medicinal product to animals.

IG/0812	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)	15/06/2017	n/a		The Agency accepted the variation to change the legal entity name of the manufacturing site used to manufacture the finished products Cerenia 10 mg/ml Solution for Injection and Draxxin 100 mg/ml and 25 mg/ml Solution for Injection.
IG/0747	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	23/03/2017	25/04/2017	SPC, Labelling and PL	The Agency accepted the variation to update the list of local representatives in the product information.
IB/0027/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size 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.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.c.2.z - Change in the specification parameters and/or limits of the immediate packaging of the AS - Other variation	18/11/2016	n/a		The Agency accepted the group of variations to add a manufacture of the maropitant citrate for Cerenia Tablets and Solution for Injection.
IAIN/0026	B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings	25/04/2016	25/04/2017	SPC and PL	The Agency accepted the variation to remove the logo of 'Pfizer' on the Cerenia 16, 24, 60 and 160mg Tablets due to the transfer of marketing authorisation to Zoetis Belgium SA.
X/0023	Annex I_2.(e) Change or addition of a new route of administration	10/04/2015	10/06/2015	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new route of administration (intravenous use) for Cerenia 10 mg/ml solution for injection for dogs and cats.
IG/0538	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	01/04/2015	n/a		The Agency accepted the variation to change the QPPV.
IG/0445	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	20/11/2014	10/06/2015	Annex II and PL	The Agency accepted the variation to change the name of the manufacturing site of the finished product responsible for batch release.
II/0022	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	08/05/2014	06/06/2014	SPC, Annex II and PL	The European Commission amended the decision granting the marketing authorisation to extend the use of Cerenia tablets from 5 to 14 consecutive days.

IG/0357/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.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	31/10/2013	n/a		The Agency accepted the variation to add two manufacturing sites for secondary packaging.
IG/0328	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	05/09/2013	n/a		The Agency accepted the variation to update the contact details of the QPPV.
II/0018	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	18/07/2013	14/08/2013	SPC and PL	The European Commission amended the decison granting the marketing authorisation to add an indication for the prevention of perioperative nausea and vomiting, and improvement in recovery from general anaesthesia after use of the μ-opiate receptor agonist morphine.
T/0019	Transfer of Marketing Authorisation	26/04/2013	14/05/2013	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Pfizer Ltd' to 'Zoetis Belgium SA'.
IB/0017/G	This was an application for a group of variations. B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the currently approved batch size	20/12/2012	n/a		The Agency accepted a group of Type IB variation to add a manufacturing site for the solution for injection.
II/0013	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	08/03/2012	13/04/2012	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new target species (cats) to the existing 10 mg/ml solution for injection.
IB/0015	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)	14/11/2011	13/01/2012	SPC	The Agency accepted a variation to extend the shelf life of the finished product from 2 years to 3 years.
II/0014	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	10/11/2011	13/01/2012	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to modify section 4.5 of the SPC (Special precautions for use in animals) and corresponding section of the package leaflet to lower the age at which the product can be safely used in dogs.
R/0012	Renewal of the marketing authorisation.	09/06/2011	05/08/2011	SPC and PL	The European Commission renewed the marketing authorisation for Cerenia.

IG/0005/G	This was an application for a group of variations. C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV	05/08/2011	05/08/2011		The Agency accepted the group of variations to change the location of the Qualified Person for Pharmacovigilance.
IB/0010	C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Changes with NO new additional data are submitted by the MAH	19/03/2010	14/10/2010	SPC and PL	The Agency accepted the variation for Cerenia 10 mg/ml solution for injection for dogs, amending the SPC with an additional safety warning in accordance with CVMP recommendations in January 2010 following assessment of PSUR data, "In very rare cases, anaphylactic type reactions (allergic oedema, urticaria, erythema, collapse, dyspnoea, pale mucous membranes) may occur."
IA/0011	A.7 - Administrative change - Deletion of manufacturing sites	08/03/2010	08/03/2010		The Agency accepted the variation to delete a manufacturing site (primary packaging).
IA/0009	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	23/02/2010	23/02/2010		The Agency accepted the variation for a minor change to the identification method used for the colourant, Sunset Yellow (E110).
IB/0008	1B-14-b Change in manufacturer active substance or starting material-new manufacturer	11/12/2009	11/12/2009		The Agency accepted the variation to change the manufacturing site for the active substance.
II/0006	II - New Indication (same therapeutic area)	15/07/2009	02/09/2009	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new indication for the tablets, i.e. "for the prevention of nausea induced by chemotherapy".
IB/0007	1B-17-a Change in the re-test period of the active substance	27/05/2009	27/05/2009		The Agency accepted the variation changing the re-test period of the active substance.
II/0005	II - New safety warning	15/10/2008	18/11/2008	SPC and PL	The European Commission amended the decision granting the marketing authorisation regarding changes of the solution for injection under "Adverse Reactions" in the wording of the SPC and the Package leaflet adding: Pain at injection site may occur.
IB/0004	1B-07-c Replacement or addition of a manufacturing site for part or all of manufacturing process	25/09/2008	25/09/2008		The Agency accepted the variation to replace the manufacturing site for the finished product (tablets).
IB/0003	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	20/11/2007	17/01/2008	SPC	The Agency accepted the variation to increase the shelf life of the tablet presentations from 2 to 3 years.
II/0002	II - Update of SPC and PL	12/12/2007	17/01/2008	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation regarding some changes in the wording of the SPC and package leaflet on the correct administration of the product. Also, some errors have been corrected.
IA/0001	1A-07-b-01 Replacement or addition of manufacturing site for part or all of manufacturing process	03/09/2007	03/09/2007		The Agency accepted the variation to add a packaging site for Cerenia Tablets for Dogs.