EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



# Varuby

## 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 |
|---|---|---|---|---|---|
| T/0015 | Transfer of Marketing Authorisation | 21/01/2019 | 11/03/2019 | SmPC, Labelling and PL | |
| IB/0013 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 13/02/2019 | n/a | | |
| N/0014 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 10/01/2019 | 11/03/2019 | 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).

**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

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| II/0007/G | This was an application for a group of variations.<br><br>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data<br>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data<br>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data | 31/10/2018 | 11/03/2019 | SmPC and PL | |
| IB/0011 | 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) | 26/09/2018 | 11/03/2019 | SmPC | |
| IB/0009 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 21/09/2018 | 11/03/2019 | SmPC | |
| PSUSA/10592 /201802 | Periodic Safety Update EU Single assessment - rolapitant | 01/09/2018 | n/a | | PRAC Recommendation - maintenance |
| IA/0010 | B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure | 08/08/2018 | n/a | | |
| IA/0006/G | This was an application for a group of variations.<br><br>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation<br>B.II.f.1.e - Stability of FP - Change to an approved | 23/04/2018 | n/a | | |

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|---|---|---|---|---|---|
| | stability protocol | | | | |
| PSUSA/10592 /201708 | Periodic Safety Update EU Single assessment - rolapitant | 12/04/2018 | n/a | | PRAC Recommendation - maintenance |
| IB/0005/G | This was an application for a group of variations.<br><br>B.I.z - Quality change - Active substance - Other variation<br>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 | 17/01/2018 | n/a | | |
| IB/0003 | C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation | 30/11/2017 | n/a | | |
| N/0002 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 02/10/2017 | 27/08/2018 | PL | |
| IAIN/0001 | 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 - N.T including batch control/testing | 01/09/2017 | 27/08/2018 | Annex II and PL | |