Veterinary Medicines Directorate

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# Post Authorisation Assessments

## MoleEcto 12.5 mg/ml Pour-on for Sheep

Vm 00879/4085

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|---|---|---|
| • | 11 March 2022 | Change(s) in the SPC, Labelling or Package Leaflet intended to implement the outcome of a PSUR. |
| • | 07 July 2021 | Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product. |
| • | 26 October 2020 | Change in test procedure for the finished product. |
| • | 09 September 2020 | Change in the address of the Marketing Authorisation Holder from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom. |
| • | 05 June 2019 | Change in the safety database of an existing pharmacovigilance system as described in the DDPS. |
| • | 15 May 2018 | Renewal - National |
| • | 06 July 2017 | Change in the name and address of a manufacturer of the finished product, also responsible for batch release. |
| • | 07 March 2017 | Introduction of a new pharmacovigilance system. |
| • | 08 November 2016 | Change of MAH, from Novartis Animal Health UK Limited to Elanco Europe Ltd. |
| • | 26 April 2016 | Change in batch size of the finished product.<br>Minor change in the manufacturing process of the finished product. |
| • | 13 October 2015 | Widening of specification limits of the active substance.<br>Changes in the test procedures. |
| • | 07 November 2014 | Change in the QPPV and the QPPV contact details.<br>Administrative changes to the DDPS. |