

Post Authorisation Assessments

MoleEcto 12.5 mg/ml Pour-on for Sheep Vm 00879/4085

22 April 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
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. Minor change in the manufacturing process of the finished product.
13 October 2015	Widening of specification limits of the active substance. Changes in the test procedures.
07 November 2014	Change in the QPPV and the QPPV contact details. Administrative changes to the DDPS.