



Post Authorisation Assessments

Crovect 1.25% w/v Pour-on Solution for Sheep Vm 52127/5079

29 April 2025	Change of Marketing Authorisation Holder from Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom to Elanco GmbH, Heinz-Lohmann Strasse 4, D-27472 Cuxhaven, Groden, Germany. Change in distributor details from Elanco Europe Ltd. to Elanco UK AH Ltd.
11 March 2022	Change(s) in the SPC, Labelling or Package Leaflet intended to implement the outcome of a PSUR.
28 April 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.
16 October 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.
03 September 2019	Change in the specification limits of the finished product.
22 August 2019	Change in the shelf-life of the finished product from 18 months to 2 years.
05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
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.
26 April 2016	Change in batch size of the finished product. Minor change in the manufacturing process of the finished product.
13 January 2016	Change of Marketing Authorisation Holder from Novartis Animal Health UK Ltd to Elanco Europe Ltd. Change in distributor details.
13 October 2015	Widening of specification limits of the active substance. Changes in the test procedures.
04 April 2012	Correction of section 4.5 of the SPC
29 June 2011	Amendment of the indications and administration dose
22 February 2011	Minor change in manufacturing process of the finished product
09 August 2010	Deletion of 2 manufacturers of the active substance
27 May 2010	Addition of a manufacturer of the active substance
30 September 2008	Change of legal category from PML to POM-VPS Changes to the SPC and Product Literature to bring in line with new legislation

16 October 2007	Change of address of MAH Change of address of Distributor
03 September 2007	Renewal
28 December 2006	Update to section 6.4 of the SPC
16 July 2004	Change of name of dosing device from 'Protector Gun' to 'Big Gun'
17 December 2002	Change of shelf life from 12 to 18 months