Veterinary Medicines Directorate

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Post Authorisation Assessments

Trigoderm Gel 0.5% w/w Fusidic Acid, 0.1% w/w Betamethasone

Vm 24883/4001

14 December 2024	Deletion of a finished specification.
04 December 2024	Removal of the distributor logo, add the ® symbol and removal of the distributor address from the leaflet at the request of the distributor. Update of mock-ups.
10 October 2023	Change in test procedure for the finished product.
23 November 2022	Minor change in the manufacturing process of the finished product.
07 November 2022	Mock ups submitted with new design for new distributor.
02 November 2022	Updated certificate of suitability from an already approved manufacturer.
16 August 2022	Change in the local Distributor. Deletion of a batch release site.
12 July 2022	Addition of identity tests for each of the preservatives for the finished product. Addition of a second identity test for the active ingredients. Minor changes to an approved test procedure for the finished product.
26 May 2022	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
22 April 2022	Addition of a site where batch control/testing takes place.
22 April 2022	Deletion of manufacturing site for a finished product.
07 January 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
25 July 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
12 February 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
20 July 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Deletion of Ph. Eur. certificates of suitability for an active substance.
01 March 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
09 June 2015	Minor change in manufacturing process of the finished product. Change in batch size of the finished product.

31 December 2014	Change in the invented name of the veterinary medicinal product from Fuciderm Gel 0.5% w/w Fusidic acid, 0.1% w/w Betamethasone to Trigoderm Gel 0.5% w/w Fusidic acid, 0.1% w/w Betamethasone.
30 October 2013	Addition of a manufacturer of an active substance
31 October 2012	Replacement of an Active Substance Master File with a Ph. Eur. Certificate of Suitability
24 October 2012	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
08 March 2011	Removal of storage condition
26 January 2011	Change of distributor
03 November 2009	Addition of a manufacturing site for the finished product
02 June 2009	Submission of an updated Ph. Eur. Certificate of Suitability for the active substance
20 May 2009	Renewal
21 March 2009	Change of manufacturer responsible for batch release Change of manufacturing site for quality control testing
16 January 2009	Change of name of MAH
28 August 2008	Change of packaging style
27 June 2008	Change of distributor
28 May 2008	Harmonisation of the SPC
14 May 2008	Deletion of a manufacturer of the active substance
01 May 2008	Change to test procedure performed on the active substance Submission of an updated Ph. Eur. Certificate of Suitability for an active substance
31 October 2007	Changes to the SPC and Product Literature to bring in line with new legislation
29 November 2005	Submission of a new ph. Eur. Certificate of Suitability for an active substance
28 October 2005	Renewal
25 July 2005	Change of name and address of the MAH
30 June 2005	Change of distributor
18 February 2005	Change of packaging colour system and product literature layout
03 December 2004	Change of product name from ‘Fuciderm’ to ‘Fuciderm Gel’
26 November 2001	Renewal
31 October 2001	Change of formulation
29 December 2000	Change of specification of the active substance
15 March 2000	Change of shelf life from 2 years to 3 years Change of storage instructions from ‘store below 25˚C, Do not freeze’ to ‘Do not store above 25˚C, Do not refrigerate or freeze’
28 January 2000	Minor change to the manufacturing process of the dosage form
21 May 1998	Change to manufacturer of the active substance