



Post Authorisation Assessments

Efex 100 mg Chewable Tablets for Dogs Vm 15052/4097

•	16 August 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance. (GB)
•	20 July 2024	Addition of a primary packaging site of a non-sterile finished product. Addition of a secondary packaging site of a non-sterile finished product.
•	14 September 2022	Change in the MAH address, from Ceva Animal Health Ltd, Unit 3, Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Ceva Animal Health Ltd, Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH United Kingdom.
•	06 October 2021	Change in the SPC, labelling or package leaflet due to new data.
•	31 October 2019	Update to the Active Substance Master File.
•	23 May 2019	Replacement of a site where batch control/testing takes place
•	09 November 2018	Change in RMS from UK to FR.
•	08 November 2018	Deletion of manufacturing site for an active substance. Changes to a test procedure for the active substance. Changes to a test procedure for the active substance. Extension of a re-test period of the active substance. Addition of a new specification parameter with its corresponding test method of an active substance. Addition of a new specification parameter with its corresponding test method of an active substance. Addition of a new specification parameter with its corresponding test method of an active substance. Addition of a new specification parameter with its corresponding test method of an active substance. Addition of a new specification parameter with its corresponding test method of an active substance. Addition of a new specification parameter with its corresponding test method of an active substance. Addition of a new specification parameter with its corresponding test method of an active substance.
•	28 June 2018	Deletion of a manufacturer responsible for batch release
•	03 May 2018	Renewal – UK as RMS
•	19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.

•	19 September 2017	Change in the name and/or address of the MAH in Spain only.
•	02 November 2016	Mock-ups approved.
•	08 September 2016	Change in the name of a manufacturer of the finished product, also responsible for batch release. Change in the name of a manufacturer of the finished product, also responsible for batch release. Change in the name of the manufacturer of the finished product.
•	06 September 2016	Change in the name and address of the MAH in Italy only.
•	29 June 2016	Introduction of a new pharmacovigilance system which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.
•	14 June 2016	Change of MAH, from Sogeval to Ceva Animal Health Ltd and Change of Distributor to Ceva Animal Health Ltd.
•	21 January 2016	To extend the shelf-life of the finished product from 2 years to 3 years.
•	24 July 2013	Change in the shelf-life of the products EFEX 10mg, EFEX 40mg and EFEX 100mg when packaged in the PVC-TE-PVDC / aluminium heat sealed blister from 21 months to 2 years.