



Post Authorisation Assessments

Eprecis 20 mg/ml Solution for Injection for Cattle, Sheep and Goats Vm 15052/5041

•	19 August 2024	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)
•	06 November 2023	Indication for Oestrus ovis added for sheep and goats. One-off alignment of the product information with version 9.0* of the QRD template.
•	20 July 2023	Substantial changes in an updated version of the ASMF.
•	September 2022	Addition of manufacturing site responsible for radiosterilisation of plastic vials.
•	27 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.
•	28 January 2022	Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Change in the manufacturing process of the finished product. Change to in-process tests or limits applied during the manufacture of the finished product.
•	15 July 2021	Addition of a new specification parameter with its corresponding test method of a starting material used in the manufacturing process of the active substance. Addition of a new specification parameter with its corresponding test method of a reagent used in the manufacturing process of the active substance.
•	30 April 2021	Variation to add new species sheep and goats.
•	27 October 2020	Renewal – UK as CMS.
•	28 January 2020	Additional supplier of the active substance.
•	17 January 2018	Addition of a second manufacturing site responsible for the radio sterilisation.

•	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.
•	30 March 2017	Change in the invented name of the veterinary medicinal product from Eprecis to Eprecis vet in Finland and Sweden only.
•	22 December 2015	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.