Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Tiacil 0.50% w/v Eye Drops, Solution

Vm 05653/4026

•	30 August 2023	SPC 4.6 reviewed to add: Rare cases of local intolerance presented as conjunctival inflammatory reactions can be observed at the onset of treatment. In rare cases acute irritation and pain may occur. These reactions are transitory, and they disappear spontaneously without any specific treatment.
•	10 March 2022	Replacement of a manufacturing site of the finished product.
•	02 October 208	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	09 May 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	17 May 2017	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Deletion of a non-significant specification parameter of the finished product. Addition of a manufacturer responsible for batch release including batch control/testing. Addition of a secondary packaging site of the finished product. Addition of a manufacturing site of the finished product.
•	12 January 2016	Submission of a new certificate of suitability for a manufacturer of the active substance.
•	29 July 2014	Update to the quality part of the dossier, including changes to the batch size, manufacturing process, specifications and several test procedures.
•	14 September 2009	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	12 June 2007	Renewal.
•	27 June 2003	Renewal.
•	08 January 2002	Removal of contra-indications.
•	18 December 2001	Change in the formulation of the finished product.
•	16 December 1999	Change of name of the distributor.
•	11 February 1999	Change of manufacturer of the active substance.
•	10 February 1999	Renewal.
•	09 October 1997	Change to the closure and dosing device.

•	12 February 1996	Change of the name of the veterinary medicinal product.