



Post Authorisation Assessments

Apitraz 500 mg Bee-hive Strips for Honey Bees Vm 20634/3000

•	22 December 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI)
•	28 April 2023	Update to the SPC & QRD following the addition of a ten week duration of treatment in the presence of brood. Update SPC/QRD in line with v.9.
•	12 April 2022	Decrease in batch size range of the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Increase in the shelf-life of the finished product as packaged for sale, from 1 year to 18 months.
•	17 November 2021	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	10 December 2020	Change in the specification parameters of the finished product.
•	22 August 2019	Change in specification parameter of the finished product.
•	25 April 2019	Tightening of specification limits of the finished product
•	27 June 2018	Renewal - UK as CMS.
•	26 April 2017	Repeat Use application to add two new member states.
•	26 April 2016	Addition of a new size strip of 250 x 48 mm. Harmonisation of the SPC between original and new CMS following a Repeat use procedure.