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Post Authorisation Assessments

Zanil Fluke Drench 34 mg/ml Oral Suspension

Vm 01708/4595

 O2 December 2020			
 18 November 2020 Change in the name and address of a manufacturer of the finished product, also responsible for batch release. 01 April 2020 Changes to a test procedure for the active substance. 05 December 2017 Changes to the SPC/product labelling/package leaflet following an Article 35 referral. 11 June 2013 To change the shelf life of the product as packaged for sale from 5 years to 3 years. 07 June 2013 Change to the specification parameters of the finished product. Approval of mock-ups for a pack size not previously marketed. 16 May 2013 Change to the batch size and batch release arrangements for the finished product. Replacement of manufacturer for the finished product with changes to the in test procedure and manufacturing process of the finished product. Updates to the SPC and product literature 05 April 2013 Change of marketing authorisation holder (MAH) from Schering-Plough Ltd to Intervet UK Ltd and to change the distributor. 13 May 2008 Renewal. 19 June 2001 Addition of a new presentation and container type. 18 October 2000 Renewal. 	•	02 December 2020	
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