

## **Post Authorisation Assessments**

## **Reproval 50mg/ml Solution for Injection for Dogs and Cats**

<ul> <li>March 2021</li> <li>Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.</li> <li>04 March 2021</li> <li>Addition of a manufacturer of the active substance or addition of a site of manufacture.</li> <li>24 December 2019</li> <li>Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.</li> <li>02 September 2019</li> <li>Replacement of a test procedure for the finished product.</li> <li>30 July 2019</li> <li>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.</li> <li>03 June 2019</li> <li>Addition of a manufacturer responsible for batch release of the finished product.</li> <li>17 May 2019</li> <li>Change in the manufacturer of a starting material used in the manufacturing process of the active substance</li> <li>20 December 2018</li> <li>Change in RMS from UK to ES.</li> <li>02 August 2018</li> <li>Minor change in the manufacturing process of the finished product.</li> <li>28 November 2014</li> <li>Update to the DDPS.</li> <li>Addition of text to the storage conditions in the SPC and</li> </ul>			
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19 September 2014 Change in distributor details.	•	19 September 2014	Change in distributor details.
02 November 2012 Change of the product name in France and Germany to	•	02 November 2012	Change of the product name in France and Germany to
Carprieve 50 mg/ml Solution for Dogs and Cats.			Carprieve 50 mg/ml Solution for Dogs and Cats.
09 October 2012 Renewal procedure.	•	09 October 2012	Renewal procedure.