

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

## **Post Authorisation Assessments**

## Bovigen Scour Emulsion for Injection for Cattle Vm 27819/4005

<ul> <li>17 November 2023 Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.</li> <li>16 October 2023 Extension of in-use shelf life from 10 hours to 10 days.</li> <li>02 July 2021 Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.</li> <li>20 August 2020 Renewal - UK as CMS.</li> <li>21 February 2020 Submission of a new Ph. Eur. certificate of suitability for a starting material (used in manufacturing process of active).</li> <li>13 November 2018 Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.</li> <li>27 March 2018 Changes to the labelling and package leaflet.</li> <li>14 February 2018 Increase in the shelf-life of the finished product as packaged for sale, from 2 to 3 years.</li> <li>14 February 2018 Change in the SPC, labelling or package leaflet due to new data.</li> <li>23 February 2016 Change in the shelf life of the finished product from 12 months to 2 years.</li> <li>22 July 2015 Repeat Use Comm.</li> </ul>			
<ul> <li>O2 July 2021 Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.</li> <li>20 August 2020 Renewal - UK as CMS.</li> <li>21 February 2020 Submission of a new Ph. Eur. certificate of suitability for a starting material (used in manufacturing process of active).</li> <li>13 November 2018 Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.</li> <li>27 March 2018 Changes to the labelling and package leaflet.</li> <li>14 February 2018 Increase in the shelf-life of the finished product as packaged for sale, from 2 to 3 years.</li> <li>14 February 2018 Change in the SPC, labelling or package leaflet due to new data.</li> <li>23 February 2016 Change in the shelf life of the finished product from 12 months to 2 years.</li> </ul>	•	17 November 2023	the summary of the PSMF not already covered
system as described in the DDPS.  20 August 2020 Renewal - UK as CMS.  21 February 2020 Submission of a new Ph. Eur. certificate of suitability for a starting material (used in manufacturing process of active).  13 November 2018 Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.  27 March 2018 Changes to the labelling and package leaflet.  14 February 2018 Increase in the shelf-life of the finished product as packaged for sale, from 2 to 3 years.  14 February 2018 Change in the SPC, labelling or package leaflet due to new data.  23 February 2016 Change in the shelf life of the finished product from 12 months to 2 years.	•	16 October 2023	Extension of in-use shelf life from 10 hours to 10 days.
<ul> <li>21 February 2020 Submission of a new Ph. Eur. certificate of suitability for a starting material (used in manufacturing process of active).</li> <li>13 November 2018 Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.</li> <li>27 March 2018 Changes to the labelling and package leaflet.</li> <li>14 February 2018 Increase in the shelf-life of the finished product as packaged for sale, from 2 to 3 years.</li> <li>14 February 2018 Change in the SPC, labelling or package leaflet due to new data.</li> <li>23 February 2016 Change in the shelf life of the finished product from 12 months to 2 years.</li> </ul>	•	02 July 2021	
<ul> <li>a starting material (used in manufacturing process of active).</li> <li>13 November 2018 Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.</li> <li>27 March 2018 Changes to the labelling and package leaflet.</li> <li>14 February 2018 Increase in the shelf-life of the finished product as packaged for sale, from 2 to 3 years.</li> <li>14 February 2018 Change in the SPC, labelling or package leaflet due to new data.</li> <li>23 February 2016 Change in the shelf life of the finished product from 12 months to 2 years.</li> </ul>	•	20 August 2020	Renewal - UK as CMS.
system as described in the DDPS.  The property 2018 of the labelling and package leaflet.  The property 2018 of the shelf-life of the finished product as packaged for sale, from 2 to 3 years.  The property 2018 of the shelf-life of the finished product as packaged for sale, from 2 to 3 years.  The property 2018 of the shelf-life of the finished product from 12 months to 2 years.	•	21 February 2020	a starting material (used in manufacturing process of
<ul> <li>14 February 2018 Increase in the shelf-life of the finished product as packaged for sale, from 2 to 3 years.</li> <li>14 February 2018 Change in the SPC, labelling or package leaflet due to new data.</li> <li>23 February 2016 Change in the shelf life of the finished product from 12 months to 2 years.</li> </ul>	•	13 November 2018	, ,
<ul> <li>packaged for sale, from 2 to 3 years.</li> <li>14 February 2018 Change in the SPC, labelling or package leaflet due to new data.</li> <li>23 February 2016 Change in the shelf life of the finished product from 12 months to 2 years.</li> </ul>	•	27 March 2018	Changes to the labelling and package leaflet.
new data.  • 23 February 2016 Change in the shelf life of the finished product from 12 months to 2 years.	•	14 February 2018	· •
months to 2 years.	•	14 February 2018	1
22 July 2015 Repeat Use Comm.	•	23 February 2016	, ,
	•	22 July 2015	Repeat Use Comm.