

VPA22033/039/001

Bimoxyl LA 150 mg/ml Suspension for Injection

Variation	Summary	Date
Vet - G.I.18	<p>VRAS - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004</p>	17/02/25
B.II.b.4.b	<p>IB - B.II.b.4.b - b) Downscaling down to 10-fold - B.II.b.4.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold</p>	16/08/22
B.II.e.1.b.2	<p>II - B.II.e.1.b.2 - 2. Sterile medicinal products and biological/ immunological medicinal products - B.II.e.1.b.2 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Sterile medicinal products and biological/ immunological medicinal products</p>	16/08/22
B.II.d.2.d	<p>IB - B.II.d.2.d - d) Other changes to a test procedure (including replacement or addition) - B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)</p>	16/08/22
B.II.b.3.a	<p>IB - B.II.b.3.a - a) Minor change in the manufacturing process - B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process</p>	16/08/22
B.II.b.1.a	<p>IAin - B.II.b.1.a - a) Secondary packaging site - B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site</p>	16/08/22
B.II.b.2.c.2	<p>IAin - B.II.b.2.c.2 - 2. Including batch control/testing - B.II.b.2.c.2 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release -</p>	16/08/22

	Including batch control/testing	
B.II.b.1.f	<p>IB - B.II.b.1.f - f) Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products - B.II.b.1.f - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products</p>	16/08/22