Veterinary Medicines Directorate

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

Post Authorisation Assessments

Panacur Granules 222 mg/g

Vm 06376/4075

•	28 June 2024	Change in legal entity of the MAH from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ, United Kingdom to Intervet International BV, Wim de Korverstraat 35, 5831 AN, Boxmeer, Netherlands.
•	14 May 2024	Updates to an ASMF and active substance specification in order to comply with an update of the relevant monograph of the Ph. Eur.
•	13 September 2023	Change in the specification limits of the finished product. Change to the method description of an in-process control test. Change to an in-process control test limit applied during the manufacture of the finished product.
•	07 July 2023	Delete odour testing specification parameter of the active substance.
•	08 March 2023	Implementation of SPC and QRD wording agreed by competent authority.
•	08 March 2023	Change in the (invented) name of the veterinary medicinal product from Panacur Granules 22.2% to Panacur Granules 222 mg/ml.
•	23 November 2022	Extension or introduction of a re-test period/storage period supported by real time data. Minor change to the restricted part of an Active Substance Master File.
•	03 March 2022	Update to QRD to reflect correct pack sizes.
•	19 August 2021	Minor change in the manufacturing process of the active substance.
•	09 June 2021	Increase in batch size (from 400 to 500 kg (with 100 kg sublots) to 600 kg (3 x 200 kg sublots) of the finished product.
•	01 April 2021	Change in the name of the MAH from Intervet UK Limited to MSD Animal Health UK Limited.
•	17 August 2020	Addition of a new specification parameter with its corresponding test method of the active substance. Minor change to the restricted part of an Active Substance Master File.
•	27 April 2020	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	08 June 2016	Reduction of the shelf life of the finished product as packaged for sale from 5 years to 36 months.
•	09 December 2015	Change(s) in the SPC, Labelling or Package Leaflet of human mediicnal products intended to impleemnt the

		outcome of a procedure concenring PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006
•	11 May 2011	Change of layout of package leaflet.
•	11 June 2008	Changes to the SPC and product literature to bring them into line with new legislation.
•	11 June 2008	Change in legal category from PML to NFA-VPS.
•	04 June 2008	Change in the site of assembler and batch release of the finished product.
•	19 March 2008	Change in the equipment used for an in-process control.
•	21 February 2008	Change in batch size of the finished product.
•	21 May 2007	Renewal
•	28 March 2007	Change in the test procedure of the finished product.
•	20 June 2005	Change in distributor.
•	09 October 2003	Renewal.
•	13 November 2002	Change in site of assembler of dosage form.
•	12 November 2001	Change in the manufacturer and distributor of dosage form.
•	03 July 2001	Addition of a distributor for Northern Ireland.
•	17 March 2000	Change in the name/address of MAH.
•	09 August 1999	Change in the size of the sterile container.