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 01708/4427

•	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.