



26 May 2023
EMA/CVMP/PhVWP/137199/2023
Veterinary Medicines Division

Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2023 (Updated monthly)

Please note that the recommendations shown in this document may not reflect the exact final wording that will appear in the actual package leaflet that still needs to be implemented by the marketing authorisation holders. When the exact wording for the package leaflet is provided with the recommendations in this document, this needs to be implemented by the marketing authorisation holders accordingly.

Previous regulatory recommendations and ongoing procedures are outlined in pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during **2022** ([EMA/CVMP/PhVWP/48138/2022](#)), during **2021** ([EMA/CVMP/PhVWP/105691/2021](#)) and during **2020** ([EMA/CVMP/PhVWP/112926/2020](#)).

NEW

Product (active substance(s))	CVMP meeting date	Recommendation – Summary of Product Characteristics (SPC)/Package Leaflet (PL) change (additions to text in bold , deletions in strikethrough)	
Apoquel (oclacitinib maleate)	15-16 May 2023	Section 3.6 of SPC and Section 7 of PL for Apoquel:	
		Target species: Dogs	
		Very rare (<1 animal / 10,000 animals treated, including isolated reports):	anaemia, lymphoma, convulsion

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<p>Galliprant (grapiprant)</p> <p><i>The text presentation has been adapted in line with changes mandated by Regulation (EU) 2019/6</i></p>	<p>21-22 March 2023</p>	<p>Section 3.6 of SPC for Galliprant:</p> <p>Target species: Dogs</p> <table border="1" data-bbox="806 379 2063 730"> <tr> <td data-bbox="806 379 1301 456">Very common (>1 animal / 10 animals treated):</td> <td data-bbox="1301 379 2063 456">Vomiting</td> </tr> <tr> <td data-bbox="806 456 1301 560">Common (1 to 10 animals / 100 animals treated):</td> <td data-bbox="1301 456 2063 560">Loose stool, Diarrhoea Inappetence</td> </tr> <tr> <td data-bbox="806 560 1301 730">Very rare (<1 animal / 10,000 animals treated, including isolated reports):</td> <td data-bbox="1301 560 2063 730">Haematemesis, Haemorrhagic diarrhoea Pancreatitis Elevated blood urea nitrogen (BUN), Elevated creatinine, Elevated liver enzymes, Hypoalbuminaemia¹, Hypoproteinaemia¹</td> </tr> </table> <p>¹ These signs were not associated with any clinically significant observations or events.</p> <p>Section 7 of PL for Galliprant:</p> <p>Target species: Dogs</p> <table border="1" data-bbox="806 922 2063 1367"> <tr> <td data-bbox="806 922 2063 970">Very common (> 1 animal / 10 animals treated):</td> </tr> <tr> <td data-bbox="806 970 2063 1034">Vomiting</td> </tr> <tr> <td data-bbox="806 1034 2063 1090">Common (1 to 10 animals / 100 animals treated):</td> </tr> <tr> <td data-bbox="806 1090 2063 1174">Loose stool, Diarrhoea Inappetence</td> </tr> <tr> <td data-bbox="806 1174 2063 1222">Very rare (<1 animal / 10,000 animals treated, including isolated reports):</td> </tr> <tr> <td data-bbox="806 1222 2063 1367">Haematemesis, Haemorrhagic diarrhoea Pancreatic inflammation Elevated blood urea nitrogen (BUN), Elevated creatinine, Elevated liver enzymes, Hypoalbuminaemia¹, Hypoproteinaemia¹</td> </tr> </table>	Very common (>1 animal / 10 animals treated):	Vomiting	Common (1 to 10 animals / 100 animals treated):	Loose stool, Diarrhoea Inappetence	Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Haematemesis, Haemorrhagic diarrhoea Pancreatitis Elevated blood urea nitrogen (BUN), Elevated creatinine, Elevated liver enzymes, Hypoalbuminaemia ¹ , Hypoproteinaemia ¹	Very common (> 1 animal / 10 animals treated):	Vomiting	Common (1 to 10 animals / 100 animals treated):	Loose stool, Diarrhoea Inappetence	Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Haematemesis, Haemorrhagic diarrhoea Pancreatic inflammation Elevated blood urea nitrogen (BUN), Elevated creatinine, Elevated liver enzymes, Hypoalbuminaemia ¹ , Hypoproteinaemia ¹
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<p>Neptra (florfenicol/terbinafine hydrochloride/mometasone furoate)</p>	<p>18-20 April 2023</p>	<p>Section 4.5 of SPC for Neptra:</p> <p><u>Special precautions for use in animals</u></p> <p>\...</p> <p>Caution should be taken to prevent the veterinary medicinal product from getting into the eyes of the dog being treated e.g. by restraining the dog’s head to prevent shaking (see section 4.9). In case of exposure to the eye, rinse with plenty of water.</p> <p>The safety and efficacy of the veterinary medicinal product in cats has not been evaluated. Post-marketing surveillance shows that the use of the product in cats can be associated with neurological signs (including ataxia, Horner’s syndrome with protrusion of membrane nictitans, miosis, anisocoria), internal ear disorders (head tilt) and systemic signs (anorexia and lethargy). The use of the veterinary medicinal product in cats should therefore be avoided.’</p> <p>Section 12 of PL for Neptra:</p> <p><u>Special precautions for use in animals</u></p> <p>\...</p> <p>Caution should be taken to prevent the veterinary medicinal product from getting into the eyes of the dog being treated e.g. by restraining the dog’s head to prevent shaking (see section “advice on correct administration”). In case of exposure to the eye, rinse with plenty of water.</p> <p>The safety and efficacy of the veterinary medicinal product in cats has not been evaluated. Post-marketing surveillance shows that the use of the product in cats can be associated with neurological signs (including ataxia, Horner’s syndrome with protrusion of membrane nictitans, miosis, anisocoria), internal ear disorders (head tilt) and systemic signs (anorexia</p>

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