15 September 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).

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

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<tr><td>Cimalgex
(cimicoxib)</td><td>11-13 July 2023</td><td>Section 4.6 of SPC for Cimalgex:
'…
Other adverse reactions including anorexia or lethargy or polyuria and/or polydipsia may also be observed on rare occasions.
…
If adverse reactions such as persistent vomiting, repeated diarrhoea, faecal occult blood, sudden weight loss, anorexia, lethargy or worsening of renal or hepatic biochemistry parameters occur, use of the product should be discontinued and appropriate monitoring and/or treatment should be put in place. Severe gastrointestinal and renal adverse events may be fatal.'
Section 6 of PL for Cimalgex:
'…
Other adverse reactions including loss of appetite or lethargy or frequent urination and/or excessive thirst may also be observed on rare occasions.
…
If adverse reactions such as persistent vomiting, repeated diarrhoea, blood in the stools, sudden weight loss, loss of appetite, lethargy or worsening of liver or kidney function results occur, use of the product should be discontinued, and the advice of your veterinary surgeon should be sought immediately. Severe adverse events in the gastrointestinal tract and kidneys may be fatal.'</td></tr>
<tr><td>Galliprant
(grapiprant)
The text presentation has been adapted in line with changes mandated by Regulation (EU) 2019/6</td><td>21-22 March 2023</td><td>Section 3.6 of SPC for Galliprant:
Target species: Dogs<table><tr><td>Very common
(>1 animal / 10 animals treated):</td><td>Vomiting</td></tr><tr><td>Common
(1 to 10 animals / 100 animals treated):</td><td>Loose stool, Diarrhoea
Inappetence</td></tr><tr><td>Very rare
(<1 animal / 10,000 animals treated, including isolated reports):</td><td>Haematemesis, Haemorrhagic diarrhoea
Pancreatitis</td></tr></table></td></tr>
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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~~)
		<table><tr><td></td><td>Elevated blood urea nitrogen (BUN), Elevated creatinine, Elevated liver enzymes, Hypoalbuminaemia[1], Hypoproteinaemia[1]</td></tr></table> [1] These signs were not associated with any clinically significant observations or events. **Section 7 of PL for Galliprant:** Target species: Dogs <table><tr><td>Very common (> 1 animal / 10 animals treated):</td></tr><tr><td>Vomiting</td></tr><tr><td>Common (1 to 10 animals / 100 animals treated):</td></tr><tr><td>Loose stool, Diarrhoea Inappetence</td></tr><tr><td>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</td></tr><tr><td>Haematemesis, Haemorrhagic diarrhoea **Pancreatic inflammation** Elevated blood urea nitrogen (BUN), Elevated creatinine, Elevated liver enzymes, Hypoalbuminaemia[1], Hypoproteinaemia[1]</td></tr></table> [1] These signs were not associated with any clinically significant observations or events.
Neptra (florfenicol/terbinafine hydrochloride/mometasone furoate)	**18-20 April 2023**	**Section 4.5 of SPC for Neptra:** <u>Special precautions for use in animals</u> '... 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. **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**

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Section 12 of PL for Neptra:
<u>Special precautions for use in animals</u>
‘...
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.
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.’</td></tr>
<tr><td>NEW
Solensia
(frunevetmab)</td><td>5-7 September 2023</td><td>Section 3.6 of SPC for Solensia:
Cats:
<table><tr><td>Common (1 to 10 animals / 100 animals treated):</td><td>localised skin reaction (e.g. alopecia, dermatitis, pruritus)</td></tr><tr><td>Rare (1 to 10 animals / 10,000 animals treated):</td><td>injection site reaction (e.g. pain and alopecia)[1]</td></tr><tr><td>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</td><td>Anaphylaxis[2]</td></tr></table></td></tr>
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[1] Mild.
[2] In case of such reactions, appropriate symptomatic treatment should be administered.

Section 7 of PL for Solensia:

Cats:

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<tr><td>Common (1 to 10 animals / 100 animals treated):</td><td>localised skin reaction (e.g. alopecia, dermatitis, pruritus)</td></tr>
<tr><td>Rare (1 to 10 animals / 10,000 animals treated):</td><td>injection site reaction (e.g. pain and alopecia)[1]</td></tr>
<tr><td>Very rare
(<1 animal / 10,000 animals treated, including isolated reports):</td><td>Anaphylaxis[2] (severe allergic reaction)</td></tr>
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[1] Mild.
[2] In case of such reactions, appropriate symptomatic treatment should be administered.
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