



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

16 September 2025  
EMA/CVMP/PhVWP/101663/2025  
Veterinary Medicines Division

## Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2025

This document is updated monthly with the adopted outcomes of the Committee for Veterinary Medicinal Products (CVMP).

Products are listed alphabetically. Updates for the latest month are identified as '**New**' in the first column of the table.

Previous regulatory recommendations and procedures are outlined in pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during **2024** ([EMA/CVMP/PhVWP/75148/2024](#)), **2023** ([EMA/CVMP/PhVWP/137199/2023](#)), **2022** ([EMA/CVMP/PhVWP/48138/2022](#)), **2021** ([EMA/CVMP/PhVWP/105691/2021](#)) and **2020** ([EMA/CVMP/PhVWP/112926/2020](#)).

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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 <del>strikethrough</del> )								
Bravecto (fluralaner)	10-12 June 2025	<p><b>Section 3.6 of SPC for Bravecto chewable tablets:</b></p> <p>Target species: Dog</p> <table border="1" data-bbox="786 539 2031 801"> <tr> <td data-bbox="786 539 2031 576"><i>Common (1 to 10 animals / 100 animals treated, including isolated reports):</i></td> </tr> <tr> <td data-bbox="786 576 2031 646">Gastrointestinal effects (such as Anorexia, Hypersalivation, Diarrhoea, Emesis) #:</td> </tr> <tr> <td data-bbox="786 646 2031 683"><i>Very rare (&lt;1 animal / 10 000 animals treated, including isolated reports):</i></td> </tr> <tr> <td data-bbox="786 683 2031 801">Lethargy; <b>Pruritus;</b> Muscle tremor, Ataxia, Convulsion.</td> </tr> </table> <p># mild and transient</p> <p><b>Section 7 of PL for Bravecto chewable tablets:</b></p> <p>Target species: Dog</p> <table border="1" data-bbox="786 962 2031 1224"> <tr> <td data-bbox="786 962 2031 999"><i>Common (1 to 10 animals / 100 animals treated, including isolated reports):</i></td> </tr> <tr> <td data-bbox="786 999 2031 1069">Gastrointestinal effects (such as Inappetence, Drooling, Diarrhoea, Vomiting) #.</td> </tr> <tr> <td data-bbox="786 1069 2031 1106"><i>Very rare (&lt;1 animal / 10 000 animals treated, including isolated reports):</i></td> </tr> <tr> <td data-bbox="786 1106 2031 1224">Apathy; <b>Itching;</b> Muscle tremor, Ataxia, Convulsion.</td> </tr> </table> <p># mild and transient</p> <p><b>Section 3.6 of SPC for Bravecto spot-on solution:</b></p>	<i>Common (1 to 10 animals / 100 animals treated, including isolated reports):</i>	Gastrointestinal effects (such as Anorexia, Hypersalivation, Diarrhoea, Emesis) #:	<i>Very rare (&lt;1 animal / 10 000 animals treated, including isolated reports):</i>	Lethargy; <b>Pruritus;</b> Muscle tremor, Ataxia, Convulsion.	<i>Common (1 to 10 animals / 100 animals treated, including isolated reports):</i>	Gastrointestinal effects (such as Inappetence, Drooling, Diarrhoea, Vomiting) #.	<i>Very rare (&lt;1 animal / 10 000 animals treated, including isolated reports):</i>	Apathy; <b>Itching;</b> Muscle tremor, Ataxia, Convulsion.
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		<p>Muscle tremor,<del>i</del> Lethargy, Anorexia,<del>i</del>, Emesis, Hypersalivation<del>u</del></p> <p><i>Very rare (&lt;1 animal / 10 000 animals treated, including isolated reports):</i></p> <p><b>Pruritus;</b> <b>Ataxia</b>, Convulsion.</p> <p># mild and transient</p> <p><b>Section 7 of PL for Bravecto spot-on solution:</b></p> <p>Target species: Cat</p> <p><i>Common (1 to 10 animals / 100 animals treated, including isolated reports):</i> Skin reactions at the application site (such as Erythema, Pruritus, Alopecia) #</p> <p><i>Uncommon (1 to 10 animals / 1,000 animals treated, including isolated reports):</i> Muscle tremor;; Apathy, Inappetence;; Vomiting, Drooling.</p> <p><i>Very rare (&lt;1 animal / 10 000 animals treated, including isolated reports):</i></p> <p><b>Itching;</b> <b>Ataxia (Incoordination)</b>, Convulsion.</p> <p># mild and transient</p>
<b>DIVENCE IBR Marker Live</b> ((Live gE- tk- double gene-deleted bovine herpesvirus type 1 (BoHV-1), strain CEDDEL))	<b>15-17 July 2025</b>	<p><b>Section 3.6 of SPC and 7 of PL for DIVENCE IBR Marker Live :</b></p> <p>Cattle:</p> <p><i>Very common (1 to 10 animals / 10 animals treated):</i> Injection site inflammation<sup>1</sup>, elevated temperature<sup>2</sup></p>

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		<p><i>Uncommon (1 to 10 animals / 1,000 animals treated):</i></p> <p>Anaphylactic-type reaction<sup>3</sup>  <b>Milk production decrease<sup>4</sup></b>  <b>Reduced food intake<sup>4</sup>, Decreased activity<sup>4</sup></b></p> <p><sup>1</sup> A slight to moderate transient injection site inflammation (up to 14 cm of diameter) may be observed, which rapidly decreases in diameter within 2 days and subsides within 2 weeks without treatment.  <sup>2</sup> An elevated temperature (mean increase 1.7 °C, in individual animals up to 2.4 °C) may occur after vaccination. This increase subsides spontaneously within 3 days.  <sup>3</sup> In cases of anaphylactic-type reactions, an appropriate symptomatic treatment should be administered.  <sup>4</sup> <b>Observed in dairy cows, mostly after application of primary dose.</b></p>
<p><b>Divence Penta</b>  (bovine viral diarrhoea (subunit), bovine parainfluenza 3 virus (inactivated), bovine respiratory syncytial virus and bovine herpesvirus type 1 (live) vaccine)</p>	<p><b>13-15 May 2025</b></p>	<p><b>Section 3.6 of SPC and section 7 of PL for Divence Penta:</b></p> <p>Cattle:</p> <p><i>Very common (&gt;1 animal / 10 animals treated):</i></p> <p>Injection site inflammation<sup>1</sup>, elevated temperature<sup>2</sup></p> <p><i>Uncommon (1 to 10 animals / 1,000 animals treated):</i></p> <p>Anaphylactic-type reaction<sup>3</sup>.  <b>Milk production decrease<sup>4</sup>.</b>  <b>Reduced food intake<sup>4</sup>, Decreased activity<sup>4</sup>.</b></p> <p><sup>1</sup> A slight to moderate transient injection site inflammation (up to 14 cm of diameter) may be observed, which rapidly decreases in diameter within 2 days and subsides within 2 weeks without treatment.  <sup>2</sup> An elevated temperature (mean increase 1.7 °C, in individual animals up to 2.4 °C) may occur after vaccination. This increase subsides spontaneously within 3 days.</p>

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<p><b>Divence Tetra</b> (bovine viral diarrhoea (subunit), bovine parainfluenza 3 virus (inactivated), bovine respiratory syncytial virus and bovine herpesvirus type 1 (live) vaccine)</p>	<p><b>09-10 September 2025</b></p>	<p><b>Section 3.6 of SPC and section 7 of PL for Divence Tetra:</b></p> <p>Cattle:</p> <table border="1" data-bbox="786 533 2029 831"> <tr> <td data-bbox="786 533 2029 571"><i>Very common (&gt;1 animal / 10 animals treated):</i></td> </tr> <tr> <td data-bbox="786 571 2029 639">Injection site inflammation<sup>1</sup>, elevated temperature<sup>2</sup></td> </tr> <tr> <td data-bbox="786 639 2029 678"><i>Uncommon (1 to 10 animals / 1,000 animals treated):</i></td> </tr> <tr> <td data-bbox="786 678 2029 831"> Anaphylactic-type reaction<sup>3</sup>.  <b>Milk production decrease<sup>4</sup>.</b>  <b>Reduced food intake<sup>4</sup>, Decreased activity<sup>4</sup>.</b> </td> </tr> </table> <p><sup>1</sup> A slight to moderate transient injection site inflammation (up to 14 cm of diameter) may be observed, which rapidly decreases in diameter within 2 days and subsides within 2 weeks without treatment.</p> <p><sup>2</sup> An elevated temperature (mean increase 1.7 °C, in individual animals up to 2.4 °C) may occur after vaccination. This increase subsides spontaneously within 3 days.</p> <p><sup>3</sup> In cases of anaphylactic-type reactions, an appropriate symptomatic treatment should be administered.</p> <p><b><sup>4</sup> Observed in dairy cows, mostly after application of primary dose.</b></p>	<i>Very common (&gt;1 animal / 10 animals treated):</i>	Injection site inflammation <sup>1</sup> , elevated temperature <sup>2</sup>	<i>Uncommon (1 to 10 animals / 1,000 animals treated):</i>	Anaphylactic-type reaction <sup>3</sup> . <b>Milk production decrease<sup>4</sup>.</b> <b>Reduced food intake<sup>4</sup>, Decreased activity<sup>4</sup>.</b>
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<p><b>Eluracat</b> (capromorelin)</p>	<p><b>15-17 July 2025</b></p>	<p><b>Section 3.6 of SPC for Eluracat:</b></p> <p>Target species: Cats</p> <table border="1" data-bbox="786 1254 2029 1318"> <tr> <td data-bbox="786 1254 2029 1289"><i>Very common (1 to 10 animals / 10 animals treated):</i></td> </tr> <tr> <td data-bbox="786 1289 2029 1318">Hypersalivation<sup>1</sup></td> </tr> </table>	<i>Very common (1 to 10 animals / 10 animals treated):</i>	Hypersalivation <sup>1</sup>		
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		<p><i>Common (1 to 10 animals / 100 animals treated):</i></p> <p>Diarrhoea, Vomiting Anaemia Skin lesions (on the mouth and chin) Dehydration, Lethargy</p> <p><b><i>Rare (1 to 10 animals / 10 000 animals treated)</i></b></p> <p><b>Anorexia</b> <b>Behavioural disorder</b></p> <p><i>Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</i></p> <p>Bradycardia, Hypotension <b>Dyspnoea</b> <b>Loss of consciousness, Sedation</b> <b>Recumbency</b> <b>Muscle weakness</b> <b>Hiding</b></p> <p><sup>1</sup> At the time of dosing and resolved within a few minutes.</p> <p><b>Section 7 of PL for Eluracat:</b></p> <p>Target species: Cats</p> <p><i>Very common (1 to 10 animals / 10 animals treated):</i></p> <p>Drooling<sup>1</sup></p> <p><i>Common (1 to 10 animals / 100 animals treated):</i></p> <p>Diarrhoea, Vomiting Anaemia Skin lesions (on the mouth and chin) Dehydration, Lethargy</p> <p><b><i>Rare (1 to 10 animals / 10 000 animals treated)</i></b></p>

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		<p><b>Anorexia (loss of appetite)</b> <b>Behavioural disorder</b></p> <hr/> <p><i>Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</i></p> <hr/> <p>Bradycardia (slow heart rate), Hypotension (low blood pressure) <b>Dyspnoea (difficulty in breathing)</b> <b>Loss of consciousness, Sedation</b> <b>Recumbency (lying down)</b> <b>Muscle weakness</b> <b>Hiding</b></p> <p><sup>1</sup> At the time of dosing and resolved within a few minutes</p>						
<p><b>Felpreva</b> (Tigolaner/Emodepside/ Praziquantel) <b>New</b></p>	<p><b>02-04</b> <b>December 2025</b></p>	<p><b>Section 3.6 of the SPC for Felpreva:</b> Cats:</p> <table border="1" data-bbox="826 844 1948 1300"> <tbody> <tr> <td data-bbox="826 844 1261 971">Common (1 to 10 animals / 100 animals treated):</td> <td data-bbox="1261 844 1948 971">Hair change (e.g. spiking)<sup>1</sup></td> </tr> <tr> <td data-bbox="826 971 1261 1099"><b>Rare</b> <b>(1 to 10 animals / 10 000 animals treated):</b></td> <td data-bbox="1261 971 1948 1099"><b>Application site reaction (e.g. scratching, erythema, hair loss, inflammation)<sup>2</sup></b></td> </tr> <tr> <td data-bbox="826 1099 1261 1300">Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</td> <td data-bbox="1261 1099 1948 1300"> <del>Application site reaction (e.g. scratching, erythema, hair thinning, inflammation)<sup>2</sup></del>  Digestive tract disorder (e.g. hypersalivation, vomiting)<sup>2,3</sup>  Neurological disorder (e.g. ataxia, tremor) </td> </tr> </tbody> </table>	Common (1 to 10 animals / 100 animals treated):	Hair change (e.g. spiking) <sup>1</sup>	<b>Rare</b> <b>(1 to 10 animals / 10 000 animals treated):</b>	<b>Application site reaction (e.g. scratching, erythema, hair loss, inflammation)<sup>2</sup></b>	Very rare (<1 animal / 10,000 animals treated, including isolated reports):	<del>Application site reaction (e.g. scratching, erythema, hair thinning, inflammation)<sup>2</sup></del> Digestive tract disorder (e.g. hypersalivation, vomiting) <sup>2,3</sup> Neurological disorder (e.g. ataxia, tremor)
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			Agitation <sup>4</sup> , Vocalisation <sup>4</sup> Inappetence <sup>4</sup>
<p><sup>1</sup> Cosmetic effect, temporary reaction, at the application site  <sup>2</sup> Mild and transient  <sup>3</sup> After licking the application site immediately following treatment.  <sup>4</sup> After licking, in individual cases</p>			
<p><b>Section 7. of the PL for Felpreva:</b></p>			
<p>Cats:</p>			
Common (1 to 10 animals / 100 animals treated):		Hair change (e.g. spiking) <sup>1</sup>	
<b>Rare</b> <b>(1 to 10 animals / 10 000 animals treated):</b>		<b>Application site reaction (e.g. scratching, reddening, hair loss, inflammation)<sup>2</sup></b>	
Very rare (<1 animal / 10,000 animals treated, including isolated reports):		<del>Application site reaction (e.g. scratching, erythema, hair thinning, inflammation)<sup>2</sup></del> Digestive tract disorder (e.g. hypersalivation, vomiting) <sup>2,3</sup> Neurological disorder (e.g. <del>ataxia</del> <b>incoordination</b> , tremor) Agitation <sup>4</sup> , Vocalisation <sup>4</sup> Inappetence <sup>4</sup>	

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<p><b>Librela</b> (Bedinvetmab)</p>	<p><b>04-06 November 2025</b></p>	<p><b>Section 3.5 of the SPC for Librela:</b></p> <p><u>Special precautions for safe use in the target species:</u>  <b>Caution should be used when treating patients with the following pre-existing conditions: immune-mediated haemolytic anaemia, immune-mediated polyarthritis, immune-mediated thrombocytopenia.</b>  <b>Caution should be used when treating patients with pre-existing seizure disorder.</b></p> <p><b>Section 3.6 of the SPC for Librela:</b>  Dogs:</p> <table border="1" data-bbox="786 855 1991 1308"> <tbody> <tr> <td data-bbox="786 855 1256 970">Uncommon (1 to 10 animals / 1,000 animals treated):</td> <td data-bbox="1256 855 1991 970">Injection site reaction (e.g. injection site swelling, injection site warmth)<sup>1</sup>.</td> </tr> <tr> <td data-bbox="786 970 1256 1126">Rare (1 to 10 animals / 10,000 animals treated):</td> <td data-bbox="1256 970 1991 1126"><b>Diarrhoea, Emesis.</b> Ataxia<sup>2</sup>. Polyuria, Urinary incontinence. Anorexia<sup>3</sup>, Lethargy, Polydipsia.</td> </tr> <tr> <td data-bbox="786 1126 1256 1308">Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</td> <td data-bbox="1256 1126 1991 1308">Hypersensitivity reaction (anaphylaxis, facial swelling, pruritus)<sup>4</sup>, Immune-mediated haemolytic anaemia, <b>Immune-mediated polyarthritis</b>, Immune-mediated thrombocytopenia. <b>Paresis, Paralysis, Seizure.</b></td> </tr> </tbody> </table>	Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site reaction (e.g. injection site swelling, injection site warmth) <sup>1</sup> .	Rare (1 to 10 animals / 10,000 animals treated):	<b>Diarrhoea, Emesis.</b> Ataxia <sup>2</sup> . Polyuria, Urinary incontinence. Anorexia <sup>3</sup> , Lethargy, Polydipsia.	Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction (anaphylaxis, facial swelling, pruritus) <sup>4</sup> , Immune-mediated haemolytic anaemia, <b>Immune-mediated polyarthritis</b> , Immune-mediated thrombocytopenia. <b>Paresis, Paralysis, Seizure.</b>
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		<p><sup>1</sup>Mild.  <sup>2</sup>Including proprioceptive ataxia.  <sup>3</sup>Often related to a transient reduced appetite.  <sup>4</sup>In case of such reactions, appropriate symptomatic treatment should be administered.</p> <p><b>Section 6. of the PL for Librela:</b></p> <p><u>Special precautions for safe use in the target species:</u>  <b>Caution should be used when treating patients with the following pre-existing conditions: low amounts of red blood cells (immune-mediated haemolytic anaemia), lameness and swelling in multiple joints (immune-mediated polyarthritis), low amounts of platelets (thrombocytes) (immune-mediated thrombocytopenia).</b>  <b>Caution should be used when treating patients with pre-existing convulsion (seizure) disorder.</b></p> <p><b>Section 7. of the PL for Librela:</b>  Dogs:</p> <table border="1" data-bbox="786 922 1991 1340"> <tbody> <tr> <td data-bbox="786 922 1256 1002">Uncommon (1 to 10 animals / 1 000 animals treated):</td> <td data-bbox="1256 922 1991 1002">Injection site reaction (e.g. injection site swelling, injection site warmth)<sup>1</sup>.</td> </tr> <tr> <td data-bbox="786 1002 1256 1161">Rare (1 to 10 animals / 10 000 animals treated):</td> <td data-bbox="1256 1002 1991 1161"><b>Diarrhoea, Vomiting.</b> Incoordination (ataxia)<sup>2</sup>. Increased need to urinate (polyuria), Urinary incontinence. Anorexia<sup>3</sup>, Lethargy, Increased thirst (polydipsia).</td> </tr> <tr> <td data-bbox="786 1161 1256 1340">Very rare (&lt;1 animal / 10 000 animals treated, including isolated reports):</td> <td data-bbox="1256 1161 1991 1340">Hypersensitivity reaction (anaphylaxis, facial swelling, itching (pruritus))<sup>4</sup>. Low amounts of red blood cells (immune- mediated haemolytic anaemia); <b>Joint pain, Lameness and Swelling in multiple joints (immune-mediated</b></td> </tr> </tbody> </table>	Uncommon (1 to 10 animals / 1 000 animals treated):	Injection site reaction (e.g. injection site swelling, injection site warmth) <sup>1</sup> .	Rare (1 to 10 animals / 10 000 animals treated):	<b>Diarrhoea, Vomiting.</b> Incoordination (ataxia) <sup>2</sup> . Increased need to urinate (polyuria), Urinary incontinence. Anorexia <sup>3</sup> , Lethargy, Increased thirst (polydipsia).	Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersensitivity reaction (anaphylaxis, facial swelling, itching (pruritus)) <sup>4</sup> . Low amounts of red blood cells (immune- mediated haemolytic anaemia); <b>Joint pain, Lameness and Swelling in multiple joints (immune-mediated</b>
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			<p><b>polyarthritis</b>); Low amounts of <b>platelets</b> (thrombocytes) (immune-mediated thrombocytopenia).  <b>Weakness (paresis), Loss of movement (paralysis), convulsion (seizure).</b></p>						
<p><b>Mhyosphere PCV ID</b> (Inactivated recombinant Mycoplasma hyopneumoniaecpPCV2, strain Nexhyon)</p>	<p><b>04-06 November 2025</b></p>	<p><b>Section 3.6 of the SPC for Mhyosphere PCV ID</b></p> <p>Pigs:</p> <table border="1" data-bbox="779 743 2022 1086"> <tbody> <tr> <td data-bbox="779 743 1267 858">           Very common (&gt; 1 animal / 10 animals treated):         </td> <td data-bbox="1267 743 2022 858">           Injection site inflammation<sup>1</sup>            Depression<sup>2</sup>  <b>Elevated temperature<sup>3</sup></b> </td> </tr> <tr> <td data-bbox="779 858 1267 971">           Common (1 to 10 animals / 100 animals treated):         </td> <td data-bbox="1267 858 2022 971">           Injection site inflammation<sup>4</sup>  <del>Elevated temperature</del> </td> </tr> <tr> <td data-bbox="779 971 1267 1086">           Very rare (&lt; 1 animal / 10 000 animals treated, including isolated reports):         </td> <td data-bbox="1267 971 2022 1086">           Anaphylactic-type reaction<sup>5</sup> </td> </tr> </tbody> </table> <p><sup>1</sup>Mild transient local reactions consisting of non-painful skin inflammations, of less than or equal to 3 cm in diameter.  <sup>2</sup>A slight depression, which subsides in less than 24 hours without treatment is very commonly observed.  <sup>3</sup><b>Increase in body temperature (mean 1.6 °C, in individual pigs less than 2.3 °C) that subsides spontaneously within 24 - 48 hours without treatment.</b></p>		Very common (> 1 animal / 10 animals treated):	Injection site inflammation <sup>1</sup> Depression <sup>2</sup> <b>Elevated temperature<sup>3</sup></b>	Common (1 to 10 animals / 100 animals treated):	Injection site inflammation <sup>4</sup> <del>Elevated temperature</del>	Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Anaphylactic-type reaction <sup>5</sup>
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		<p><del><sup>3</sup>Moderate inflammation (between 3–5 cm) at the inoculation site is observed from 4 hours post-vaccination to day three. These local reactions can be observed during the first week after vaccination and last for 1 to 5 days. One or two weeks later, these local reactions can reappear lasting for 1 to 7 days. Local reactions disappear completely within approximately 3 weeks after vaccination without treatment.</del></p> <p><b><sup>4</sup>Slight to moderate inflammation (between 0.3-5 cm) at the inoculation site can be observed during the first week after vaccination. One or two weeks later, these local reactions can reappear. Local reactions disappear completely within approximately 3 weeks after vaccination without treatment.</b></p> <p><del><sup>4</sup>Slight transient increase in body temperature (mean 0.6 °C, in individual pigs less than 2 °C) that subsides spontaneously within 48 hours without treatment.</del></p> <p><sup>5</sup>Anaphylactic-type reactions (e.g. vomiting, circulatory disorders, dyspnoea) which might be life-threatening, may occur in some sensitive animals. Under these circumstances, appropriate symptomatic treatment should be administered.</p> <p><b>Section 7. of the PL for Mhyosphere PCV ID</b></p> <p>Pigs:</p> <table border="1" data-bbox="786 943 2022 1283"> <tbody> <tr> <td data-bbox="786 943 1267 1058">Very common (&gt; 1 animal / 10 animals treated):</td> <td data-bbox="1267 943 2022 1058">Injection site inflammation<sup>1</sup> Depression<sup>2</sup> <b>Elevated temperature<sup>3</sup></b></td> </tr> <tr> <td data-bbox="786 1058 1267 1173">Common (1 to 10 animals / 100 animals treated):</td> <td data-bbox="1267 1058 2022 1173">Injection site inflammation<sup>4</sup> <del>Elevated temperature</del></td> </tr> <tr> <td data-bbox="786 1173 1267 1283">Very rare (&lt; 1 animal / 10 000 animals treated, including isolated reports):</td> <td data-bbox="1267 1173 2022 1283">Anaphylactic-type reaction (severe allergic reaction)<sup>5</sup></td> </tr> </tbody> </table>	Very common (> 1 animal / 10 animals treated):	Injection site inflammation <sup>1</sup> Depression <sup>2</sup> <b>Elevated temperature<sup>3</sup></b>	Common (1 to 10 animals / 100 animals treated):	Injection site inflammation <sup>4</sup> <del>Elevated temperature</del>	Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Anaphylactic-type reaction (severe allergic reaction) <sup>5</sup>
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<p><b>Neptra</b> (florfenicol, terbinafine and mometasone)</p>	<p><b>15-17 July 2025</b></p>	<p><b>Section 3.6 of SPC and 7 of PL for Neptra ear drops solution:</b></p> <p>Target species: Dog</p> <table border="1" data-bbox="788 1126 2029 1337"> <tr> <td data-bbox="788 1126 2029 1161"> <p><i>Very rare (&lt;1 animal / 10 000 animals treated, including isolated reports):</i></p> </td> </tr> <tr> <td data-bbox="788 1161 2029 1337"> <p>Application site erythema, Application site inflammation, Application site pain<sup>1</sup> Hyperactivity, Vocalisation<sup>1</sup> Emesis Deafness<sup>2</sup>, Impaired hearing<sup>2</sup>, Internal ear disorder, Head shake<sup>1</sup> Eye disorder (e.g. blepharospasm, conjunctivitis, corneal ulcer, eye irritation, keratoconjunctivitis sicca).</p> </td> </tr> </table>	<p><i>Very rare (&lt;1 animal / 10 000 animals treated, including isolated reports):</i></p>	<p>Application site erythema, Application site inflammation, Application site pain<sup>1</sup> Hyperactivity, Vocalisation<sup>1</sup> Emesis Deafness<sup>2</sup>, Impaired hearing<sup>2</sup>, Internal ear disorder, Head shake<sup>1</sup> Eye disorder (e.g. blepharospasm, conjunctivitis, corneal ulcer, eye irritation, keratoconjunctivitis sicca).</p>
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		<p>Ataxia, <b>Facial paralysis</b>, Nystagmus Anorexia</p> <p><sup>1</sup>Observed to occur shortly after product administration. <sup>2</sup>Mainly in elderly animals</p>
<p><b>Osrnia</b> (Terbinafine/Florfenicol/ Betamethasone acetate)</p>	<p><b>11-13 March 2025</b></p>	<p><b>Section 4.5 of SPC and section 12 of the PL:</b></p> <p>The veterinary medicinal product may be irritating to eyes. Avoid accidental contact to the dog’s eyes. If accidental ocular exposure does occur, the eyes should be flushed thoroughly with water for 10 to 15 minutes. If clinical signs develop, seek veterinary advice.</p> <p><del>In very rare cases, eye disorders such as keratoconjunctivitis sicca and corneal ulcers have been reported in treated dogs, in absence of eye contact with the product. Although a causal relationship with the veterinary medicinal product was not definitively established. Owners should be recommended to monitor ocular signs (such as squinting, redness and discharge) in the hours and days following the product application, and to promptly consult a veterinarian in case such signs appear.</del> <b>See section 4.6 [PL: section 6] for details on ocular adverse events in dogs.</b></p> <p><b>Section 4.6 of SPC and section 6 of the PL:</b></p> <p>Deafness or impaired hearing, usually temporary, have been reported after use in very rare cases in dogs, mainly in elderly animals, in post authorisation experience.</p> <p>Application site reactions (i.e. erythema, pain, pruritus, oedema and ulcer) have been reported in very rare cases, in post authorisation experience.</p>

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		<p>Hypersensitivity reactions including facial oedema, urticaria and shock have been reported in very rare cases, in post authorisation experience.</p> <p><b>In very rare cases, eye disorders such as neurogenic keratoconjunctivitis sicca, keratoconjunctivitis sicca, corneal ulcer, blepharospasm, eye redness and ocular discharge have been reported in treated dogs (see also section 4.5 [PL: section 12] – special precautions for use in animals).</b></p> <p><b>Ataxia, internal ear disorder (mainly head tilt), facial paralysis and nystagmus have been reported in very rare cases in post authorisation experience.</b></p>				
<p><b>Yurvac RHD</b> (rabbit haemorrhagic disease and RHDV2 vaccine (recombinant))</p>	<p><b>7-9 October 2025</b></p>	<p><b>Section 3.6 of the SPC and section 7. of the PL for Yurvac RHD:</b></p> <p>Rabbits, including pet (dwarf) rabbits:</p> <table border="1" data-bbox="801 699 2051 879"> <tbody> <tr> <td data-bbox="801 699 1279 759">Very common (&gt; 1 animal / 10 animals treated):</td> <td data-bbox="1279 699 2051 759">Elevated temperature<sup>1</sup> Injection site inflammation<sup>2</sup></td> </tr> <tr> <td data-bbox="801 759 1279 879"><b>Very rare (&lt; 1 animal / 10 000 animals treated, including isolated reports):</b></td> <td data-bbox="1279 759 2051 879"><b>Anorexia<sup>3</sup></b> <b>Intestinal stasis<sup>3</sup></b></td> </tr> </tbody> </table> <p><sup>1</sup> The highest individual rectal temperature increase was 1.15 °C which returned to normal values 24 hours later.</p> <p><sup>2</sup> Inflammation (&lt; 2 cm) at the injection can be observed. These local reactions gradually reduce and disappear without need for treatment.</p> <p><sup>3</sup> <b>Transient.</b></p>	Very common (> 1 animal / 10 animals treated):	Elevated temperature <sup>1</sup> Injection site inflammation <sup>2</sup>	<b>Very rare (&lt; 1 animal / 10 000 animals treated, including isolated reports):</b>	<b>Anorexia<sup>3</sup></b> <b>Intestinal stasis<sup>3</sup></b>
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