



19 June 2024  
EMA/CVMP/PhVWP/75148/2024  
Veterinary Medicines Division

## Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2024 (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 **2023** ([EMA/CVMP/PhVWP/137199/2023](#)), 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 <del>strikethrough</del> )
AdTab (lotilaner)	18-19 June 2024	<b>Section 3.6 of SPC for AdTab:</b> Target species: Cats  Very rare ( $<1$ animal / 10,000 animals treated, including isolated reports):  <b>Hyperactivity<sup>1,2</sup></b> Vomiting <sup>2</sup> <b>Ataxia, Muscle tremor</b> <b>Tachypnoea</b>

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands  
**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)  
**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



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> )			
			<b>Pruritus<sup>1,2</sup></b> <b>Anorexia, Lethargy</b>		
		<sup>1</sup> Mild and transient. <sup>2</sup> Typically resolves without treatment.  <b>Section 7 of PL for AdTab:</b> Target species: Cats  <i>Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</i> <b>Hyperactivity<sup>1,2</sup></b> Vomiting <sup>2</sup> <b>Ataxia (incoordination), Muscle tremor</b> <b>Tachypnoea (rapid shallow breathing)</b> <b>Pruritus (itching)<sup>1,2</sup></b> <b>Anorexia (appetite loss), Lethargy</b>  <sup>1</sup> Mild and transient. <sup>2</sup> Typically resolves without treatment.			
<b>AdTab</b> (lotilaner)	<b>13-14 February</b> <b>2024</b>	<b>Section 3.6 of SPC for AdTab:</b> Target species: Dogs  <table border="1" data-bbox="792 1050 2049 1273"> <tr> <td data-bbox="792 1050 1424 1273"> Very rare  (&lt;1 animal / 10,000 animals treated, including isolated reports) </td> <td data-bbox="1429 1050 2049 1273"> Diarrhoea<sup>1,2</sup>, <b>Bloody diarrhoea<sup>1</sup></b>, Vomiting<sup>1,2</sup>;  Anorexia<sup>1,2</sup>, Lethargy<sup>2</sup>, <b>Polydipsia<sup>1,2</sup></b>;  Ataxia<sup>3</sup>, Convulsion<sup>3</sup>, Tremor<sup>3</sup>;  <b>Pruritus<sup>1,2</sup></b>;  <b>Inappropriate urination<sup>1</sup>, Polyuria<sup>1,2</sup>,</b>  <b>Urinary incontinence<sup>1,2</sup>.</b> </td> </tr> </table> <sup>1</sup> Mild and transient <sup>2</sup> Typically resolves without treatment <sup>3</sup> Transient in most cases		Very rare (<1 animal / 10,000 animals treated, including isolated reports)	Diarrhoea <sup>1,2</sup> , <b>Bloody diarrhoea<sup>1</sup></b> , Vomiting <sup>1,2</sup> ; Anorexia <sup>1,2</sup> , Lethargy <sup>2</sup> , <b>Polydipsia<sup>1,2</sup></b> ; Ataxia <sup>3</sup> , Convulsion <sup>3</sup> , Tremor <sup>3</sup> ; <b>Pruritus<sup>1,2</sup></b> ; <b>Inappropriate urination<sup>1</sup>, Polyuria<sup>1,2</sup>,</b> <b>Urinary incontinence<sup>1,2</sup>.</b>
Very rare (<1 animal / 10,000 animals treated, including isolated reports)	Diarrhoea <sup>1,2</sup> , <b>Bloody diarrhoea<sup>1</sup></b> , Vomiting <sup>1,2</sup> ; Anorexia <sup>1,2</sup> , Lethargy <sup>2</sup> , <b>Polydipsia<sup>1,2</sup></b> ; Ataxia <sup>3</sup> , Convulsion <sup>3</sup> , Tremor <sup>3</sup> ; <b>Pruritus<sup>1,2</sup></b> ; <b>Inappropriate urination<sup>1</sup>, Polyuria<sup>1,2</sup>,</b> <b>Urinary incontinence<sup>1,2</sup>.</b>				

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> )								
		<p><b>Section 7 of PL for AdTab:</b></p> <p>Target species: Dogs</p> <table border="1" data-bbox="801 427 2040 643"> <tr> <td colspan="2" data-bbox="801 427 2040 464"><i>Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</i></td> </tr> <tr> <td data-bbox="801 464 1429 571">Diarrhoea<sup>1,2</sup>, <b>Bloody diarrhoea</b><sup>1</sup>, Vomiting<sup>1,2</sup>; Anorexia<sup>1,2</sup>, Lethargy<sup>2</sup>, <b>Polydipsia (increased thirst)</b><sup>1,2</sup>; Ataxia<sup>3</sup>, Convulsion<sup>3</sup>, Tremor<sup>3</sup>;</td> <td data-bbox="1429 464 2040 571"></td> </tr> <tr> <td data-bbox="801 571 1429 608"><b>Pruritus (itching)</b><sup>1,2</sup>;</td> <td data-bbox="1429 571 2040 608"></td> </tr> <tr> <td data-bbox="801 608 1429 643"><b>Inappropriate urination</b><sup>1</sup>, <b>Polyuria (increased urination)</b><sup>1,2</sup>, <b>Urinary incontinence</b><sup>1,2</sup></td> <td data-bbox="1429 608 2040 643"></td> </tr> </table> <p><sup>1</sup>Mild and transient. <sup>2</sup>Typically resolves without treatment. <sup>3</sup>Transient in most cases.</p>	<i>Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</i>		Diarrhoea <sup>1,2</sup> , <b>Bloody diarrhoea</b> <sup>1</sup> , Vomiting <sup>1,2</sup> ; Anorexia <sup>1,2</sup> , Lethargy <sup>2</sup> , <b>Polydipsia (increased thirst)</b> <sup>1,2</sup> ; Ataxia <sup>3</sup> , Convulsion <sup>3</sup> , Tremor <sup>3</sup> ;		<b>Pruritus (itching)</b> <sup>1,2</sup> ;		<b>Inappropriate urination</b> <sup>1</sup> , <b>Polyuria (increased urination)</b> <sup>1,2</sup> , <b>Urinary incontinence</b> <sup>1,2</sup>	
<i>Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</i>										
Diarrhoea <sup>1,2</sup> , <b>Bloody diarrhoea</b> <sup>1</sup> , Vomiting <sup>1,2</sup> ; Anorexia <sup>1,2</sup> , Lethargy <sup>2</sup> , <b>Polydipsia (increased thirst)</b> <sup>1,2</sup> ; Ataxia <sup>3</sup> , Convulsion <sup>3</sup> , Tremor <sup>3</sup> ;										
<b>Pruritus (itching)</b> <sup>1,2</sup> ;										
<b>Inappropriate urination</b> <sup>1</sup> , <b>Polyuria (increased urination)</b> <sup>1,2</sup> , <b>Urinary incontinence</b> <sup>1,2</sup>										
<b>NEW</b> Credelio (lotilaner)	<b>18-19 June 2024</b>	<p><b>Section 3.6 of SPC for Credelio:</b></p> <p>Target species: Cats</p> <table border="1" data-bbox="790 898 2056 1123"> <tr> <td data-bbox="790 898 1429 1123"> <p>Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</p> </td> <td data-bbox="1429 898 2056 1123"> <p><b>Hyperactivity</b><sup>1,2</sup> Vomiting<sup>2</sup> <b>Ataxia, Muscle tremor</b> <b>Tachypnoea</b> <b>Pruritus</b><sup>1,2</sup> <b>Anorexia, Lethargy</b></p> </td> </tr> </table> <p><sup>1</sup>Mild and transient. <sup>2</sup>Typically resolves without treatment.</p> <p><b>Section 7 of PL for Credelio:</b></p> <p>Target species: Cats</p> <table border="1" data-bbox="801 1342 2040 1372"> <tr> <td data-bbox="801 1342 2040 1372"><i>Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</i></td> </tr> </table>	<p>Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</p>	<p><b>Hyperactivity</b><sup>1,2</sup> Vomiting<sup>2</sup> <b>Ataxia, Muscle tremor</b> <b>Tachypnoea</b> <b>Pruritus</b><sup>1,2</sup> <b>Anorexia, Lethargy</b></p>	<i>Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</i>					
<p>Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</p>	<p><b>Hyperactivity</b><sup>1,2</sup> Vomiting<sup>2</sup> <b>Ataxia, Muscle tremor</b> <b>Tachypnoea</b> <b>Pruritus</b><sup>1,2</sup> <b>Anorexia, Lethargy</b></p>									
<i>Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</i>										

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> )			
		<p><b>Hyperactivity</b><sup>1,2</sup> Vomiting<sup>2</sup> <b>Ataxia (incoordination), Muscle tremor</b> <b>Tachypnoea (rapid shallow breathing)</b> <b>Pruritus (itching)</b><sup>1,2</sup> <b>Anorexia (appetite loss), Lethargy</b></p> <p><sup>1</sup>Mild and transient. <sup>2</sup>Typically resolves without treatment.</p>			
<p><b>Credelio</b> (lotilaner)</p>	<p><b>13-14 February 2024</b></p>	<p><b>Section 3.6 of SPC for Credelio:</b> Target species: Dogs</p> <table border="1" data-bbox="786 719 2054 946"> <tr> <td data-bbox="786 719 1422 946"> <p>Very rare (<i>&lt;1 animal / 10,000 animals treated, including isolated reports</i>)</p> </td> <td data-bbox="1429 719 2054 946"> <p>Diarrhoea<sup>1,2</sup>, <b>Bloody diarrhoea</b><sup>1</sup>, Vomiting<sup>1,2</sup>; Anorexia<sup>1,2</sup>, Lethargy<sup>2</sup>, <b>Polydipsia</b><sup>1,2</sup>; Ataxia<sup>3</sup>, Convulsion<sup>3</sup>, Tremor<sup>3</sup>; <b>Pruritus</b><sup>1,2</sup>; <b>Inappropriate urination</b><sup>1</sup>, <b>Polyuria</b><sup>1,2</sup>, <b>Urinary incontinence</b><sup>1,2</sup>.</p> </td> </tr> </table> <p><sup>1</sup>Mild and transient. <sup>2</sup>Typically resolves without treatment. <sup>3</sup>Transient in most cases.</p> <p><b>Section 7 of PL for Credelio:</b> Target species: Dogs</p> <table border="1" data-bbox="786 1198 2054 1375"> <tr> <td data-bbox="786 1198 2054 1375"> <p><i>Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</i> Diarrhoea<sup>1,2</sup>, <b>Bloody diarrhoea</b><sup>1</sup>, Vomiting<sup>1,2</sup>; Anorexia<sup>1,2</sup>, Lethargy<sup>2</sup>, <b>Polydipsia (increased thirst)</b><sup>1,2</sup>; Ataxia<sup>3</sup>, Convulsion<sup>3</sup>, Tremor<sup>3</sup>; <b>Pruritus (itching)</b><sup>1,2</sup>;</p> </td> </tr> </table>	<p>Very rare (<i>&lt;1 animal / 10,000 animals treated, including isolated reports</i>)</p>	<p>Diarrhoea<sup>1,2</sup>, <b>Bloody diarrhoea</b><sup>1</sup>, Vomiting<sup>1,2</sup>; Anorexia<sup>1,2</sup>, Lethargy<sup>2</sup>, <b>Polydipsia</b><sup>1,2</sup>; Ataxia<sup>3</sup>, Convulsion<sup>3</sup>, Tremor<sup>3</sup>; <b>Pruritus</b><sup>1,2</sup>; <b>Inappropriate urination</b><sup>1</sup>, <b>Polyuria</b><sup>1,2</sup>, <b>Urinary incontinence</b><sup>1,2</sup>.</p>	<p><i>Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</i> Diarrhoea<sup>1,2</sup>, <b>Bloody diarrhoea</b><sup>1</sup>, Vomiting<sup>1,2</sup>; Anorexia<sup>1,2</sup>, Lethargy<sup>2</sup>, <b>Polydipsia (increased thirst)</b><sup>1,2</sup>; Ataxia<sup>3</sup>, Convulsion<sup>3</sup>, Tremor<sup>3</sup>; <b>Pruritus (itching)</b><sup>1,2</sup>;</p>
<p>Very rare (<i>&lt;1 animal / 10,000 animals treated, including isolated reports</i>)</p>	<p>Diarrhoea<sup>1,2</sup>, <b>Bloody diarrhoea</b><sup>1</sup>, Vomiting<sup>1,2</sup>; Anorexia<sup>1,2</sup>, Lethargy<sup>2</sup>, <b>Polydipsia</b><sup>1,2</sup>; Ataxia<sup>3</sup>, Convulsion<sup>3</sup>, Tremor<sup>3</sup>; <b>Pruritus</b><sup>1,2</sup>; <b>Inappropriate urination</b><sup>1</sup>, <b>Polyuria</b><sup>1,2</sup>, <b>Urinary incontinence</b><sup>1,2</sup>.</p>				
<p><i>Very rare (&lt;1 animal / 10,000 animals treated, including isolated reports):</i> Diarrhoea<sup>1,2</sup>, <b>Bloody diarrhoea</b><sup>1</sup>, Vomiting<sup>1,2</sup>; Anorexia<sup>1,2</sup>, Lethargy<sup>2</sup>, <b>Polydipsia (increased thirst)</b><sup>1,2</sup>; Ataxia<sup>3</sup>, Convulsion<sup>3</sup>, Tremor<sup>3</sup>; <b>Pruritus (itching)</b><sup>1,2</sup>;</p>					

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> )
		<p><b>Inappropriate urination<sup>1</sup>, Polyuria (increased urination)<sup>1,2</sup>, Urinary incontinence<sup>1,2</sup></b></p> <p><sup>1</sup>Mild and transient.  <sup>2</sup>Typically resolves without treatment.  <sup>3</sup>Transient in most cases.</p>
<p><b>Strangvac</b>  (Recombinant  <i>Streptococcus equi</i> protein  CCE, Recombinant  <i>Streptococcus equi</i> protein  Eq85, Recombinant  <i>Streptococcus equi</i> protein  IdeE)</p>	<p><b>13-14 February  2024</b></p>	<p><b>Section 4.6 of SPC and section 6 of PL for Strangvac:</b></p> <p>"A transient increase in body temperature of up to 2.6°C for one to five days is very common following vaccination.</p> <p><b>Ocular discharge which may be mucopurulent and present from both eyes is very commonly seen for one to five days after vaccination.</b></p> <p>Transient local tissue reactions at the injection site, characterised by heat, pain and swelling (approximately 5 cm diameter) are very commonly seen and last for up to five days. Frequency of injection site reactions are more pronounced after the second primary dose and further doses.</p> <p><b>Injection site swellings exceeding 8 cm are uncommonly seen; the majority of these have been observed in the pectoral muscle. Muscle stiffness around the injection site occurs uncommonly.</b></p> <p>Loss of appetite and demeanour changes for one day are common.</p> <p><del>Ocular discharge which may be mucopurulent and present from both eyes is very commonly seen for one to five days after vaccination.</del> Anaphylactic-like reactions occur in very rare cases.</p> <p>..."</p>