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SCIENCE MEDICINES HEALTH

10 January 2025
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Veterinary Medicines Division

Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2024

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 **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](#)).

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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)				
AdTab (lotilaner)	18-19 June 2024	<p>Section 3.6 of SPC for AdTab:</p> <p>Target species: Cats</p> <table><tr><td><i>Very rare (< 1 animal / 10,000 animals treated, including isolated reports):</i></td></tr><tr><td>Hyperactivity^{1,2} Vomiting² Ataxia, Muscle tremor Tachypnoea Pruritus^{1,2} Anorexia, Lethargy</td></tr></table> <p>¹Mild and transient. ²Typically resolves without treatment.</p> <p>Section 7 of PL for AdTab:</p> <p>Target species: Cats</p> <table><tr><td><i>Very rare (< 1 animal / 10,000 animals treated, including isolated reports):</i></td></tr><tr><td>Hyperactivity^{1,2} Vomiting² Ataxia (incoordination), Muscle tremor Tachypnoea (rapid shallow breathing) Pruritus (itching)^{1,2} Anorexia (appetite loss), Lethargy</td></tr></table> <p>¹Mild and transient. ²Typically resolves without treatment.</p>	<i>Very rare (< 1 animal / 10,000 animals treated, including isolated reports):</i>	Hyperactivity ^{1,2} Vomiting ² Ataxia, Muscle tremor Tachypnoea Pruritus ^{1,2} Anorexia, Lethargy	<i>Very rare (< 1 animal / 10,000 animals treated, including isolated reports):</i>	Hyperactivity ^{1,2} Vomiting ² Ataxia (incoordination), Muscle tremor Tachypnoea (rapid shallow breathing) Pruritus (itching) ^{1,2} Anorexia (appetite loss), Lethargy
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AdTab (lotilaner)	13-14 February 2024	Section 3.6 of SPC for AdTab: Target species: Dogs <div><i>Very rare (< 1 animal / 10,000 animals treated, including isolated reports):</i></div> <div>Diarrhoea^{1,2}, Bloody diarrhoea¹, Vomiting^{1,2}; Anorexia^{1,2}, Lethargy², Polydipsia^{1,2}; Ataxia³, Convulsion³, Tremor³; Pruritus^{1,2}; Inappropriate urination¹, Polyuria^{1,2}, Urinary incontinence^{1,2}</div> ¹ Mild and transient ² Typically resolves without treatment ³ Transient in most cases
		Section 7 of PL for AdTab: Target species: Dogs <div><i>Very rare (< 1 animal / 10,000 animals treated, including isolated reports):</i></div> <div>Diarrhoea^{1,2}, Bloody diarrhoea¹, Vomiting^{1,2}; Anorexia^{1,2}, Lethargy², Polydipsia (increased thirst)^{1,2}; Ataxia³, Convulsion³, Tremor³; Pruritus (itching)^{1,2}; Inappropriate urination¹, Polyuria (increased urination)^{1,2}, Urinary incontinence^{1,2}</div> ¹ Mild and transient. ² Typically resolves without treatment. ³ Transient in most cases.

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)				
Credelio (lotilaner)	18-19 June 2024	<p>Section 3.6 of SPC for Credelio:</p> <p>Target species: Cats</p> <table><tr><td><i>Very rare (< 1 animal / 10,000 animals treated, including isolated reports):</i></td></tr><tr><td>Hyperactivity^{1,2} Vomiting² Ataxia, Muscle tremor Tachypnoea Pruritus^{1,2} Anorexia, Lethargy</td></tr></table> <p>¹Mild and transient. ²Typically resolves without treatment.</p> <p>Section 7 of PL for Credelio:</p> <p>Target species: Cats</p> <table><tr><td><i>Very rare (< 1 animal / 10,000 animals treated, including isolated reports):</i></td></tr><tr><td>Hyperactivity^{1,2} Vomiting² Ataxia (incoordination), Muscle tremor Tachypnoea (rapid shallow breathing) Pruritus (itching)^{1,2} Anorexia (appetite loss), Lethargy</td></tr></table> <p>¹Mild and transient. ²Typically resolves without treatment.</p>	<i>Very rare (< 1 animal / 10,000 animals treated, including isolated reports):</i>	Hyperactivity ^{1,2} Vomiting ² Ataxia, Muscle tremor Tachypnoea Pruritus ^{1,2} Anorexia, Lethargy	<i>Very rare (< 1 animal / 10,000 animals treated, including isolated reports):</i>	Hyperactivity ^{1,2} Vomiting ² Ataxia (incoordination), Muscle tremor Tachypnoea (rapid shallow breathing) Pruritus (itching) ^{1,2} Anorexia (appetite loss), Lethargy
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Eluracat (Capromorelin tartrate) New	8-10 October 2024	Sections 3.3, 3.5 and 3.6 of SPC for Eluracat: <u>Contraindications</u> Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Do not use in cats with hypersomatotropism (acromegaly). <u>Special precautions for safe use in the target species:</u> Use with caution in cats with hypersomatotropism (acromegaly). <u>Adverse events</u> <table border="1"><tr><td>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</td></tr><tr><td>Bradycardia, Hypotension</td></tr></table> Sections 5, 6 and 7 of PL for Eluracat: <u>Contraindications</u> Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Do not use in cats with hypersomatotropism (acromegaly). <u>Special precautions for safe use in the target species:</u> Use with caution in cats with hypersomatotropism (acromegaly). <u>Adverse events</u> <table border="1"><tr><td>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</td></tr><tr><td>Bradycardia (slow heart rate), Hypotension (low blood pressure)</td></tr></table>	Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Bradycardia, Hypotension	Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Bradycardia (slow heart rate), Hypotension (low blood pressure)
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Bradycardia (slow heart rate), Hypotension (low blood pressure)						
Credelio (lotilaner)	13-14 February 2024	Section 3.6 of SPC for Credelio:				

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		<p>Target species: Dogs</p> <div> <p><i>Very rare (< 1 animal / 10,000 animals treated, including isolated reports):</i></p> <p>Diarrhoea^{1,2}, Bloody diarrhoea¹, Vomiting^{1,2}; Anorexia^{1,2}, Lethargy², Polydipsia^{1,2}; Ataxia³, Convulsion³, Tremor³; Pruritus^{1,2}; Inappropriate urination¹, Polyuria^{1,2}, Urinary incontinence^{1,2}</p> <p>¹Mild and transient. ²Typically resolves without treatment. ³Transient in most cases.</p> <p>Section 7 of PL for Credelio:</p> <p>Target species: Dogs</p> <div> <p><i>Very rare (< 1 animal / 10,000 animals treated, including isolated reports):</i></p> <p>Diarrhoea^{1,2}, Bloody diarrhoea¹, Vomiting^{1,2}; Anorexia^{1,2}, Lethargy², Polydipsia (increased thirst)^{1,2}; Ataxia³, Convulsion³, Tremor³; Pruritus (itching)^{1,2}; Inappropriate urination¹, Polyuria (increased urination)^{1,2}, Urinary incontinence^{1,2}</p> <p>¹Mild and transient. ²Typically resolves without treatment. ³Transient in most cases.</p> </div> </div>
Librela (bedinvetmab) New	3-5 December 2024	<p>Section 3.6 of SPC for Librela:</p> <div> <p><i>Rare (1 to 10 animals / 10,000 animals treated):</i></p> </div>

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		<p>Ataxia². Polyuria, Urinary incontinence. Anorexia³, Lethargy, Polydipsia.</p> <p>¹Mild. ²Including proprioceptive ataxia. ³Often related to a transient reduced appetite.</p> <p>Section 7 of PL for Librela:</p> <p><i>Rare (1 to 10 animals / 10,000 animals treated):</i></p> <p>Incoordination (ataxia²), Increased need to urinate (polyuria), Urinary incontinence, Anorexia³, Lethargy, Increased thirst (polydipsia).</p> <p>¹Mild. ²Including incoordination due to reduced sensory function (proprioceptive ataxia). ³Often related to a transient reduced appetite.</p>
Profender (emodepside; praziquantel)	16-18 July 2024	<p>Section 4.6 of SPC and section 6 of PL for Profender:</p> <p>Salivation, vomiting and diarrhoea may occur in very rare cases. Mild and transient neurological disorders such as ataxia or tremor may occur in very rare cases. These effects are thought to occur as a result of the cat licking the application site immediately after treatment. In very rare cases following administration of Profender transient alopecia, pruritus and/or inflammation were observed at the application site. In very rare occasions, behavioural disorders, such as hyperactivity, anxiety and vocalisation may occur. Anorexia and lethargy have been reported in very rare occasions.</p>
Strangvac (Recombinant	13-14 February 2024	<p>Section 4.6 of SPC and section 6 of PL for Strangvac:</p>

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<i>Streptococcus equi</i> protein CCE, Recombinant <i>Streptococcus equi</i> protein Eq85, Recombinant <i>Streptococcus equi</i> protein IdeE)		<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>Ocular discharge which may be mucopurulent and present from both eyes is very commonly seen for one to five days after vaccination.</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>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.</p> <p>Loss of appetite and demeanour changes for one day are common.</p> <p>Ocular discharge which may be mucopurulent and present from both eyes is very commonly seen for one to five days after vaccination. Anaphylactic-like reactions occur in very rare cases.</p> <p>..."</p>