



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 July 2024
EMA/CVMP/PhVWP/75148/2024
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 border="1" data-bbox="788 475 2038 727"> <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 border="1" data-bbox="788 943 2038 1195"> <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 | <p>Section 3.6 of SPC for AdTab:</p> <p>Target species: Dogs</p> <div style="border: 1px solid black; padding: 5px;"> <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> </div> <p>¹Mild and transient ²Typically resolves without treatment ³Transient in most cases</p> <p>Section 7 of PL for AdTab:</p> <p>Target species: Dogs</p> <div style="border: 1px solid black; padding: 5px;"> <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> </div> <p>¹Mild and transient. ²Typically resolves without treatment. ³Transient in most cases.</p> |

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| Credelio (lotilaner) | 18-19 June 2024 | <p>Section 3.6 of SPC for Credelio:</p> <p>Target species: Cats</p> <div data-bbox="786 368 2029 627" style="border: 1px solid black; padding: 5px;"> <p><i>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</i></p> <p>Hyperactivity^{1,2} Vomiting² Ataxia, Muscle tremor Tachypnoea Pruritus^{1,2} Anorexia, Lethargy</p> </div> <p>¹Mild and transient. ²Typically resolves without treatment.</p> <p>Section 7 of PL for Credelio:</p> <p>Target species: Cats</p> <div data-bbox="786 842 2029 1101" style="border: 1px solid black; padding: 5px;"> <p><i>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</i></p> <p>Hyperactivity^{1,2} Vomiting² Ataxia (incoordination), Muscle tremor Tachypnoea (rapid shallow breathing) Pruritus (itching)^{1,2} Anorexia (appetite loss), Lethargy</p> </div> <p>¹Mild and transient. ²Typically resolves without treatment.</p> |

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| Credelio (lotilaner) | 13-14 February 2024 | <p>Section 3.6 of SPC for Credelio:</p> <p>Target species: Dogs</p> <table border="1" data-bbox="788 368 2038 595"> <tr> <td><i>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</i></td> </tr> <tr> <td>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}</td> </tr> </table> <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> <table border="1" data-bbox="788 847 2038 1074"> <tr> <td><i>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</i></td> </tr> <tr> <td>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}</td> </tr> </table> <p>¹Mild and transient. ²Typically resolves without treatment. ³Transient in most cases.</p> | <i>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</i> | Diarrhoea ^{1,2} , Bloody diarrhoea ¹ , Vomiting ^{1,2} ; Anorexia ^{1,2} , Lethargy ² , Polydipsia ^{1,2} ; Ataxia ³ , Convulsion ³ , Tremor ³ ; Pruritus ^{1,2} ; Inappropriate urination ¹ , Polyuria ^{1,2} , Urinary incontinence ^{1,2} | <i>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</i> | Diarrhoea ^{1,2} , Bloody diarrhoea ¹ , Vomiting ^{1,2} ; Anorexia ^{1,2} , Lethargy ² , Polydipsia (increased thirst) ^{1,2} ; Ataxia ³ , Convulsion ³ , Tremor ³ ; Pruritus (itching) ^{1,2} ; Inappropriate urination ¹ , Polyuria (increased urination) ^{1,2} , Urinary incontinence ^{1,2} |
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| Profender New (emodepside; praziquantel) | 16-18 July 2024 | Section 4.6 of SPC and section 6 of PL for Profender: 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. |
| Strangvac (Recombinant <i>Streptococcus equi</i> protein CCE, Recombinant <i>Streptococcus equi</i> protein Eq85, Recombinant <i>Streptococcus equi</i> protein IdeE) | 13-14 February 2024 | Section 4.6 of SPC and section 6 of PL for Strangvac: "A transient increase in body temperature of up to 2.6°C for one to five days is very common following vaccination. Ocular discharge which may be mucopurulent and present from both eyes is very commonly seen for one to five days after vaccination. 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. 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. Loss of appetite and demeanour changes for one day are common. 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. ... " |