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).
<table>
<thead>
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<th>Product (active substance(s))</th>
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| AdTab (lotilaner)             | 18-19 June 2024   | **Section 3.6 of SPC for AdTab:**  
Target species: Cats  

| Very rare (<1 animal / 10,000 animals treated, including isolated reports):  
| Hyperactivity\(^{1,2}\)  
Vomiting\(^2\)  
Ataxia, Muscle tremor  
Tachypnoea  
Pruritus\(^{1,2}\)  
Anorexia, Lethargy  
\(^1\)Mild and transient.  
\(^2\)Typically resolves without treatment.  

**Section 7 of PL for AdTab:**  
Target species: Cats  

| Very rare (<1 animal / 10,000 animals treated, including isolated reports):  
| Hyperactivity\(^{1,2}\)  
Vomiting\(^2\)  
Ataxia (incoordination), Muscle tremor  
Tachypnoea (rapid shallow breathing)  
Pruritus (itching)\(^{1,2}\)  
Anorexia (appetite loss), Lethargy  
\(^1\)Mild and transient.  
\(^2\)Typically resolves without treatment.  

### Product (active substance(s))

| AdTab (lotilaner) |

| CVMP meeting date | Recommendation – Summary of Product Characteristics (SPC)/Package Leaflet (PL) change (additions to text in bold, deletions in strikethrough) |

| AdTab (lotilaner) | 13-14 February 2024 |

### Section 3.6 of SPC for AdTab:

**Target species:** Dogs

| Very rare (<1 animal / 10,000 animals treated, including isolated reports): |

| Diarrhoea¹,², Bloody diarrhoea¹, Vomiting¹,²; |
| Anorexia¹,², Lethargy², Polydipsia¹,²; |
| Ataxia³, Convulsion³, Tremor³; |
| Pruritus¹,²; |
| Inappropriate urination¹, Polyuria¹,², Urinary incontinence¹,² |

¹Mild and transient.
²Typically resolves without treatment.
³Transient in most cases.

### Section 7 of PL for AdTab:

**Target species:** Dogs

| Very rare (<1 animal / 10,000 animals treated, including isolated reports): |

| Diarrhoea¹,², Bloody diarrhoea¹, Vomiting¹,²; |
| Anorexia¹,², Lethargy², Polydipsia (increased thirst)¹,²; |
| Ataxia³, Convulsion³, Tremor³; |
| Pruritus (itching)¹,²; |
| Inappropriate urination¹, Polyuria (increased urination)¹,², Urinary incontinence¹,² |

¹Mild and transient.
²Typically resolves without treatment.
³Transient in most cases.
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| Credelio (lotilaner)          | 18-19 June 2024   | **Section 3.6 of SPC for Credelio:**  
|                               |                   | Target species: Cats  
|                               |                   | *Very rare (<1 animal / 10,000 animals treated, including isolated reports):*  
|                               |                   | **Hyperactivity**<sup>1,2</sup>  
|                               |                   | Vomiting<sup>2</sup>  
|                               |                   | Ataxia, Muscle tremor  
|                               |                   | Tachypnoea  
|                               |                   | Pruritus<sup>1,2</sup>  
|                               |                   | Anorexia, Lethargy  
|                               |                   | <sup>1</sup>Mild and transient.  
|                               |                   | <sup>2</sup>Typically resolves without treatment.  
|                               |                   | **Section 7 of PL for Credelio:**  
|                               |                   | Target species: Cats  
|                               |                   | *Very rare (<1 animal / 10,000 animals treated, including isolated reports):*  
|                               |                   | **Hyperactivity**<sup>1,2</sup>  
|                               |                   | Vomiting<sup>2</sup>  
|                               |                   | Ataxia (incoordination), Muscle tremor  
|                               |                   | Tachypnoea (rapid shallow breathing)  
|                               |                   | Pruritus (itching)<sup>1,2</sup>  
|                               |                   | Anorexia (appetite loss), Lethargy  
|                               |                   | <sup>1</sup>Mild and transient.  
|                               |                   | <sup>2</sup>Typically resolves without treatment.  

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Target species: Dogs  
**Very rare (<1 animal / 10,000 animals treated, including isolated reports):**  
Diarrhoea<sup>1,2</sup>, **Bloody diarrhoea**<sup>1</sup>, Vomiting<sup>1,2</sup>;  
Anorexia<sup>1,2</sup>, Lethargy<sup>2</sup>, **Polydipsia**<sup>1,2</sup>;  
Ataxia<sup>3</sup>, Convulsion<sup>3</sup>, Tremor<sup>3</sup>;  
**Pruritus**<sup>1,2</sup>;  
**Inappropriate urination**<sup>1</sup>, Polyuria<sup>1,2</sup>, Urinary incontinence<sup>1,2</sup>  
<sup>1</sup>Mild and transient.  
<sup>2</sup>Typically resolves without treatment.  
<sup>3</sup>Transient in most cases.  

**Section 7 of PL for Credelio:**  
Target species: Dogs  
**Very rare (<1 animal / 10,000 animals treated, including isolated reports):**  
Diarrhoea<sup>1,2</sup>, **Bloody diarrhoea**<sup>1</sup>, Vomiting<sup>1,2</sup>;  
Anorexia<sup>1,2</sup>, Lethargy<sup>2</sup>, **Polydipsia (increased thirst)**<sup>1,2</sup>;  
Ataxia<sup>3</sup>, Convulsion<sup>3</sup>, Tremor<sup>3</sup>;  
**Pruritus (itching)**<sup>1,2</sup>;  
**Inappropriate urination**<sup>1</sup>, Polyuria (increased urination)<sup>1,2</sup>, Urinary incontinence<sup>1,2</sup>  
<sup>1</sup>Mild and transient.  
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| **Profender** (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 *Streptococcus equi* protein CCE, Recombinant *Streptococcus equi* protein Eq85, Recombinant *Streptococcus equi* 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.  
..."