



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

21 April 2026  
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European Medicines Agency

## Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2026

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 **2025** ([EMA/CVMP/PhVWP/101663/2025](#)), **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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**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands  
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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> )								
<b>Bravecto</b> (fluralaner)	<b>10-12 February 2026</b>	<p><b>Section 3.5 of SPC and Section 6 of PL for Bravecto 150 mg/ml powder and solvent for suspension for injection for dogs:</b></p> <p><u>Special precautions to be taken by the person administering the veterinary medicinal product to animals:</u> Hypersensitivity reactions to fluralaner or benzyl alcohol in humans have been reported, which can potentially be serious. Also, injection site reactions may occur. Care should be taken to avoid accidental self-injection and dermal exposure when administering this veterinary medicinal product. In case of accidental self-injection with adverse effects, hypersensitivity reactions or injection site reactions, contact a physician and show the label or package leaflet. <b>If accidental skin exposure occurs, wash the skin immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with clean water.</b> Wash hands after use.</p> <p>This veterinary medicinal product is to be administered only by veterinarians or under their close supervision.</p> <p><b>Section 3.6 of SPC for Bravecto 150 mg/ml powder and solvent for suspension for injection for dogs:</b></p> <table border="1" data-bbox="748 863 1951 1246"> <tbody> <tr> <td data-bbox="748 863 1341 940">Common (1 to 10 animals / 100 animals treated)</td> <td data-bbox="1341 863 1951 940">Injection site swelling<sup>1</sup></td> </tr> <tr> <td data-bbox="748 940 1341 1054">Uncommon (1 to 10 animals / 1,000 animals treated)</td> <td data-bbox="1341 940 1951 1054">Decreased appetite; Tiredness; Hyperaemic mucous membranes.</td> </tr> <tr> <td data-bbox="748 1054 1341 1133"><b>Rare (1 to 10 animals / 10 000 animals treated)</b></td> <td data-bbox="1341 1054 1951 1133"><b>Emesis, Diarrhoea.</b></td> </tr> <tr> <td data-bbox="748 1133 1341 1246">Very rare (&lt;1 animal / 10 000 animals treated, including isolated reports)</td> <td data-bbox="1341 1133 1951 1246">Muscle tremor, Ataxia, Convulsion; <b>Allergic oedema, Hypersensitivity reaction; Pruritus.</b></td> </tr> </tbody> </table> <p><sup>1</sup>Palpable and/or visual swellings, non-inflammatory, non-painful, self-resolving over time</p>	Common (1 to 10 animals / 100 animals treated)	Injection site swelling <sup>1</sup>	Uncommon (1 to 10 animals / 1,000 animals treated)	Decreased appetite; Tiredness; Hyperaemic mucous membranes.	<b>Rare (1 to 10 animals / 10 000 animals treated)</b>	<b>Emesis, Diarrhoea.</b>	Very rare (<1 animal / 10 000 animals treated, including isolated reports)	Muscle tremor, Ataxia, Convulsion; <b>Allergic oedema, Hypersensitivity reaction; Pruritus.</b>
Common (1 to 10 animals / 100 animals treated)	Injection site swelling <sup>1</sup>									
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		<p><b>Section 7 of PL for Bravecto 150 mg/ml powder and solvent for suspension for injection for dogs:</b></p> <table border="1" data-bbox="750 375 1982 758"> <tr> <td data-bbox="750 375 1220 486">Common (1 to 10 animals / 100 animals treated):</td> <td data-bbox="1220 375 1982 486">Injection site swelling<sup>1</sup></td> </tr> <tr> <td data-bbox="750 486 1220 566">Uncommon (1 to 10 animals / 1 000 animals treated):</td> <td data-bbox="1220 486 1982 566">Decreased appetite, Tiredness, Hyperaemic mucous membranes.</td> </tr> <tr> <td data-bbox="750 566 1220 646"><b>Rare (1 to 10 animals / 10 000 animals treated):</b></td> <td data-bbox="1220 566 1982 646"><b>Emesis (vomiting), Diarrhoea.</b></td> </tr> <tr> <td data-bbox="750 646 1220 758">Very rare (&lt;1 animal / 10 000 animals treated, including isolated reports):</td> <td data-bbox="1220 646 1982 758">Muscle tremor, Ataxia (Incoordination), Convulsion, <b>Allergic oedema (swelling), Hypersensitivity reaction, Pruritus (itching).</b></td> </tr> </table> <p><sup>1</sup>Palpable and/or visual swellings, non-inflammatory, non-painful, self-resolving over time</p>	Common (1 to 10 animals / 100 animals treated):	Injection site swelling <sup>1</sup>	Uncommon (1 to 10 animals / 1 000 animals treated):	Decreased appetite, Tiredness, Hyperaemic mucous membranes.	<b>Rare (1 to 10 animals / 10 000 animals treated):</b>	<b>Emesis (vomiting), Diarrhoea.</b>	Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Muscle tremor, Ataxia (Incoordination), Convulsion, <b>Allergic oedema (swelling), Hypersensitivity reaction, Pruritus (itching).</b>
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Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Muscle tremor, Ataxia (Incoordination), Convulsion, <b>Allergic oedema (swelling), Hypersensitivity reaction, Pruritus (itching).</b>									
<p><b>Coxevac</b> (Coxiella burnetii vaccine (inactivated))</p>	<p><b>10-12 February 2026</b></p>	<p><b>Section 3.5 of SPC for COXEVAC suspension for injection for cattle, goats and sheep</b> <u>Special precautions for safe use in the target species:</u> It is advisable to vaccinate all the animals in the herd at the same time. <del>Under field conditions, vaccination with COXEVAC has commonly been followed by a decrease in milk production in goats. Since stress could contribute to this adverse reaction, appropriate precautions should be taken to reduce stress as much as possible during the administration of the product.</del></p> <p><b>Section 3.6 of SPC and Section 7 of PL for COXEVAC suspension for injection for cattle, goats and sheep</b> <u>Cattle:</u></p> <table border="1" data-bbox="750 1252 1960 1404"> <tr> <td data-bbox="750 1252 1220 1332">Very common (&gt;1 animal / 10 animals treated):</td> <td data-bbox="1220 1252 1960 1332">Injection site swelling*</td> </tr> <tr> <td data-bbox="750 1332 1220 1404">Rare</td> <td data-bbox="1220 1332 1960 1404">Lethargy, Hyperthermia, Anorexia <b>Milk production decrease**</b></td> </tr> </table>	Very common (>1 animal / 10 animals treated):	Injection site swelling*	Rare	Lethargy, Hyperthermia, Anorexia <b>Milk production decrease**</b>				
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		(1 to 10 animals / 10,000 animals treated):	
		<p>* Palpable, of 9 to 10 cm diameter maximum, which may last for 17 days, reduces gradually and disappears without need for treatment.</p> <p><b>** Since stress could contribute to this adverse reaction, appropriate precautions should be taken to reduce stress as much as possible during the administration of the product.</b></p>	
		<p><u>Goats:</u></p>	
		Very common (>1 animal / 10 animals treated):	Injection site swelling* Hyperthermia**
		<b>Common (1 to 10 animals / 100 animals treated):</b>	<b>Milk production decrease***</b>
		Uncommon (1 to 10 animals / 1,000 animals treated):	Lethargy, Malaise, Anorexia
		Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea
		<p>* Palpable, of 3 to 4 cm diameter maximum, which may last for 14 days, reduces and disappears without need for treatment.</p> <p>** For 4 days post-vaccination.</p> <p><b>*** Since stress could contribute to this adverse reaction, appropriate precautions should be taken to reduce stress as much as possible during the administration of the product.</b></p>	
		<p><u>Sheep:</u></p>	
		Very common (>1 animal / 10 animals treated):	Injection site inflammation, application site thickening*

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		<p>Rare (1 to 10 animals / 10,000 animals treated):</p>	<p>Lethargy, Hyperthermia, Anorexia <b>Milk production decrease**</b></p> <p>* Palpable, of 5 cm diameter maximum, which may last for 14 days, reduces and disappears without need for treatment. Reactions are expected to be more severe after the second injection.</p> <p><b>** Since stress could contribute to this adverse reaction, appropriate precautions should be taken to reduce stress as much as possible during the administration of the product.</b></p> <p>Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also section "Contact details" of the package leaflet.</p> <p><b>Section 3.7 of SPC for COXEVAC suspension for injection for cattle, goats and sheep</b></p> <p>Pregnancy and lactation: <u>Cattle and goats:</u></p> <p>The safety of the veterinary medicinal product has not been established during pregnancy. The vaccine can be used during lactation. <del>Under field conditions, vaccination with COXEVAC has been followed by a decrease in milk production, commonly in goats and rarely in cattle. Since stress could contribute to this adverse reaction, appropriate precautions should be taken to reduce stress as much as possible during the administration of the product.</del></p> <p><b>Section 6 of PL for COXEVAC suspension for injection for cattle, goats and sheep</b></p> <p><u>Special precautions for safe use in the target species:</u></p> <p>Vaccination of animals already infected at the time of vaccination will have no adverse reaction. No efficacy data are available concerning the use of COXEVAC in male animals. However, in safety laboratory trials, the use of COXEVAC in males proved to be safe. In the case that it is decided to vaccinate the whole herd, it is advisable to vaccinate the male animals at the same time.</p>

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		<p>There are no benefits of the vaccine (as described in the indications for cattle), when used in infected and/or pregnant cows.</p> <p>The biological significance of the levels of reduction shown in shedding in cattle, goats and sheep is not known.</p> <p>It is advisable to vaccinate all the animals in the herd at the same time.</p> <p><del>Under field conditions, vaccination with COXEVAC has commonly been followed by a decrease in milk production in goats. Since stress could contribute to this adverse reaction, appropriate precautions should be taken to reduce stress as much as possible during the administration of the product.</del></p> <p><u>Pregnancy and lactation:</u> <u>Cattle and goats:</u></p> <p>The safety of the veterinary medicinal product has not been established during pregnancy.</p> <p><del>Under field conditions, vaccination with COXEVAC has been followed by a decrease in milk production, commonly in goats and rarely in cattle. Since stress could contribute to this adverse reaction, appropriate precautions should be taken to reduce stress as much as possible during the administration of the product.</del></p> <p>The vaccine can be used during lactation.</p>
<p><b>Senvelgo</b> (velagliflozin) <b>New</b></p>	<p><b>EC decision date:</b> <b>16 April 2026</b></p>	<p><b>Section 3.5 of SPC and section 6 of PL for Senvelgo:</b> <u>Prior to treatment start:</u> <b>Diabetic ketoacidosis (DKA) is a potential complication of diabetes mellitus. DKA (including euglycaemic DKA) is also a commonly reported adverse event during treatment with the veterinary medicinal product, and fatal cases have been reported. Therefore, screening for DKA must be performed and a check for ketone bodies in the urine or blood is required prior to use and during treatment.</b> Treatment should not be initiated or resumed, if ketone bodies at concentrations indicative of DKA are present, <b>as treatment with the veterinary medicinal product in cats with ongoing DKA could contribute to a worsened clinical condition and is therefore contraindicated (see section 3.5).</b></p>

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		<p><u>Initial monitoring recommendations (first two weeks):</u>  Discontinue treatment immediately in the event of confirmed or suspected diabetic ketoacidosis (DKA) or diabetic ketonuria and investigate accordingly. <b>Delay in diagnosis and treatment of DKA may result in increased severity of DKA and fatality.</b>  (...) Checking for ketones is required at the initiation of therapy and every 1 to 3 days for the first two weeks <b>(preferably daily for the first 7 days)</b> as well as whenever the cat is showing clinical signs of illness, such as reduced food intake, acute vomiting or decreased activity. <b>Owners are encouraged to bring cats to the veterinary clinic/practice for monitoring of ketones</b> as screening for the presence of ketone bodies should ideally be performed on <del>plasma</del> <b>blood</b> at the veterinary clinic. <b>Alternatively, ketone bodies</b> can be checked by the cat owner at home <b>either using a ketone meter on blood or</b> by dipping a respective urine test stripe into the cat's urine, e.g. in the cat litter. If ketones are detected, therapy should be discontinued and the cat evaluated by a veterinarian at once.</p> <p><u>Routine monitoring recommendations:</u>  (...) Whenever clinical signs of DKA occur, <b>immediate veterinary consultation is necessary, as</b> the cat should be evaluated for the presence of ketone bodies (e.g. ketonuria and/or ketonaemia) indicating DKA. If the cat develops DKA, ketonuria or ketosis or if the cat's clinical condition declines or blood glucose or fructosamine values worsen after initial improvement, additional diagnostics or alternative therapies may be required. Evaluation of haematology, serum chemistry, urinalysis and hydration status are recommended.</p> <p><b>Section 3.6 of SPC and Section 7 of PL for Senvelgo:</b>  Cats:</p> <table border="1" data-bbox="750 1098 1955 1407"> <tbody> <tr> <td data-bbox="750 1098 1258 1294">Very common (&gt;1 animal / 10 animals treated):</td> <td data-bbox="1258 1098 1955 1294">Diarrhoea or loose stool<sup>1</sup> Polydipsia or polyuria<sup>2</sup> Weight loss<sup>3</sup> Dehydration<sup>4</sup> Vomiting<sup>5</sup></td> </tr> <tr> <td data-bbox="750 1294 1258 1407">Common (1 to 10 animals / 100 animals treated):</td> <td data-bbox="1258 1294 1955 1407">Diabetic ketoacidosis (DKA)<sup>6</sup> Diabetic ketonuria<sup>6</sup></td> </tr> </tbody> </table>	Very common (>1 animal / 10 animals treated):	Diarrhoea or loose stool <sup>1</sup> Polydipsia or polyuria <sup>2</sup> Weight loss <sup>3</sup> Dehydration <sup>4</sup> Vomiting <sup>5</sup>	Common (1 to 10 animals / 100 animals treated):	Diabetic ketoacidosis (DKA) <sup>6</sup> Diabetic ketonuria <sup>6</sup>
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			<table border="1"> <tr> <td data-bbox="1240 256 1630 376">Urinary tract infection (UTI) Hypersalivation<sup>7</sup> Hypercalcaemia<sup>8</sup></td> <td data-bbox="1630 256 2049 376"></td> </tr> </table> <p data-bbox="741 408 2049 592">(...) <sup>6</sup> In case of DKA or diabetic ketonuria: Stop treatment and initiate insulin therapy. <b>Fatal outcome was reported in post-marketing cases reporting DKA during treatment with Senvelgo.</b> See also sections 3.3 and 3.5. (...)</p>	Urinary tract infection (UTI) Hypersalivation <sup>7</sup> Hypercalcaemia <sup>8</sup>									
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<b>Solensia</b> (frunevetmab) <b>New</b>	<b>14-16 April 2026</b>	<p data-bbox="741 592 2049 679"><b>Section 3.6 of SPC for Solensia:</b> Cats:</p> <table border="1" data-bbox="763 679 1917 978"> <tr> <td data-bbox="763 679 1240 767">Common (1 to 10 animals / 100 animals treated):</td> <td data-bbox="1240 679 1917 767">Alopecia, Dermatitis, Pruritus</td> </tr> <tr> <td data-bbox="763 767 1240 855">Rare (1 to 10 animals / 10 000 animals treated):</td> <td data-bbox="1240 767 1917 855">Injection site reaction (e.g. pain and alopecia)<sup>1</sup> Skin disorders (e.g. skin scab, skin sore)</td> </tr> <tr> <td data-bbox="763 855 1240 978">Very rare (&lt;1 animal / 10 000 animals treated, including isolated reports):</td> <td data-bbox="1240 855 1917 978">Anaphylaxis<sup>2</sup> <b>Ataxia</b> <b>Polyuria</b> <b>Polydipsia</b></td> </tr> </table> <p data-bbox="741 1010 2049 1042"><sup>1</sup>Mild. <sup>2</sup>In case of such reactions, appropriate symptomatic treatment should be administered.</p> <p data-bbox="741 1121 2049 1209"><b>Section 7 of PL for Solensia:</b> Cats:</p> <table border="1" data-bbox="763 1209 1895 1383"> <tr> <td data-bbox="763 1209 1240 1297">Common (1 to 10 animals / 100 animals treated):</td> <td data-bbox="1240 1209 1895 1297">Alopecia (<b>hair loss</b>), Dermatitis, Pruritus (<b>itching</b>)</td> </tr> <tr> <td data-bbox="763 1297 1240 1383">Rare (1 to 10 animals / 10 000 animals treated):</td> <td data-bbox="1240 1297 1895 1383">Injection site reaction (e.g. pain and alopecia)<sup>1</sup> Skin disorders (e.g. skin scab, skin sore)</td> </tr> </table>		Common (1 to 10 animals / 100 animals treated):	Alopecia, Dermatitis, Pruritus	Rare (1 to 10 animals / 10 000 animals treated):	Injection site reaction (e.g. pain and alopecia) <sup>1</sup> Skin disorders (e.g. skin scab, skin sore)	Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylaxis <sup>2</sup> <b>Ataxia</b> <b>Polyuria</b> <b>Polydipsia</b>	Common (1 to 10 animals / 100 animals treated):	Alopecia ( <b>hair loss</b> ), Dermatitis, Pruritus ( <b>itching</b> )	Rare (1 to 10 animals / 10 000 animals treated):	Injection site reaction (e.g. pain and alopecia) <sup>1</sup> Skin disorders (e.g. skin scab, skin sore)
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		Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylaxis (severe allergic reaction) <sup>2</sup> <b>Ataxia (incoordination)</b> <b>Polyuria (increased urination)</b> <b>Polydipsia (increased thirst)</b>
<b>Versican Plus DHPPI/L4</b> (Canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine (inactivated))	<b>10-12 February 2026</b>	<b>Section 3.6 of SPC and Section 7 of PL for Versican Plus DHPPI/L4 lyophilisate and suspension for suspension for injection for dogs:</b>	
		Dogs:	
		Common (1 to 10 animals / 100 animals treated):	Injection site swelling <sup>1</sup>
		Rare (1 to 10 animals / 10,000 animals treated):	<b>Injection site lump, Injection site mass, Injection site nodule</b> Hypersensitivity reaction <sup>2</sup> (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting) Anorexia, Decreased activity
		Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hyperthermia, Lethargy, Malaise Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthritis
<b>Versican Plus Pi/L4</b> (Canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine (inactivated))	<b>10-12 February 2026</b>	<b>Section 3.6 of SPC and Section 7 of PL for Versican Plus Pi/L4 lyophilisate and suspension for suspension for injection for dogs:</b>	
		Dogs:	
		Common (1 to 10 animals / 100 animals treated):	Injection site swelling <sup>1</sup>

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		Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction <sup>2</sup> (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting) Anorexia, Decreased activity
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<b>Versican Plus Pi/L4R</b> (Canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine and rabies vaccine (inactivated))	<b>10-12 February 2026</b>	<b>Section 3.6 of SPC and Section 7 of PL for Versican Plus Pi/L4R lyophilisate and suspension for suspension for injection for dogs:</b> Dogs:	
		Common (1 to 10 animals / 100 animals treated):	Injection site swelling <sup>1</sup>
		Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction <sup>2</sup> (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting) Anorexia, Decreased activity
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<b>Versican Plus L4</b> (Canine leptospirosis vaccine (inactivated))	<b>10-12 February 2026</b>	<b>Section 3.6 of SPC and Section 7 of PL for Versican Plus L4 lyophilisate and suspension for suspension for injection for dogs:</b> Dogs:	

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		Common (1 to 10 animals / 100 animals treated):	Injection site swelling <sup>1</sup>
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		Very rare (<1 animal / 10,000 animals treated, including isolated reports):	<b>Injection site lump, Injection site mass, Injection site nodule</b> Hyperthermia, Lethargy, Malaise Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthritis

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>Yurvac RHD</b> (rabbit haemorrhagic disease and RHDV2 vaccine (recombinant))	<b>10-12 February 2026</b>	<p><b>Section 3.6 of SPC and Section 7 of PL for YURVAC RHD:</b>            Rabbits, including pet (dwarf) rabbits:</p> <table border="1" data-bbox="748 376 1957 568"> <tr> <td data-bbox="748 376 1223 453">Very common (&gt; 1 animal/ 10 animals treated):</td> <td data-bbox="1223 376 1957 453">Elevated temperature<sup>1</sup> Injection site inflammation<sup>2</sup></td> </tr> <tr> <td data-bbox="748 453 1223 568">Very rare (&lt; 1 animal/ 10 000 animals treated, including isolated reports):</td> <td data-bbox="1223 453 1957 568">Anorexia<sup>3</sup>, <b>Lethargy<sup>3</sup></b> Intestinal stasis<sup>3</sup> <b>Lameness<sup>3</sup></b></td> </tr> </table> <p><sup>1</sup> <del>The highest individual rectal temperature increase was</del> <b>Up to 1.15 °C</b> <del>which returned</del> <b>returning</b> to normal values <b>within</b> 24 hours <del>later</del>.</p> <p><sup>2</sup> Inflammation (&lt; 2 cm) at the injection <del>may can</del> be observed. These local reactions gradually reduce and disappear without need for treatment.</p> <p><sup>3</sup> Transient.</p>	Very common (> 1 animal/ 10 animals treated):	Elevated temperature <sup>1</sup> Injection site inflammation <sup>2</sup>	Very rare (< 1 animal/ 10 000 animals treated, including isolated reports):	Anorexia <sup>3</sup> , <b>Lethargy<sup>3</sup></b> Intestinal stasis <sup>3</sup> <b>Lameness<sup>3</sup></b>
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