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SCIENCE MEDICINES HEALTH

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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](#)).

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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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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)								
Bravecto (fluralaner) New	10-12 February 2026	<p>Section 3.5 of SPC and Section 6 of PL for Bravecto 150 mg/ml powder and solvent for suspension for injection for dogs:</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. If accidental skin exposure occurs, wash the skin immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with clean water. Wash hands after use.</p> <p>This veterinary medicinal product is to be administered only by veterinarians or under their close supervision.</p> <p>Section 3.6 of SPC for Bravecto 150 mg/ml powder and solvent for suspension for injection for dogs:</p> <table><tr><td>Common (1 to 10 animals / 100 animals treated)</td><td>Injection site swelling¹</td></tr><tr><td>Uncommon (1 to 10 animals / 1,000 animals treated)</td><td>Decreased appetite; Tiredness; Hyperaemic mucous membranes.</td></tr><tr><td>Rare (1 to 10 animals / 10 000 animals treated)</td><td>Emesis, Diarrhoea.</td></tr><tr><td>Very rare (<1 animal / 10 000 animals treated, including isolated reports)</td><td>Muscle tremor, Ataxia, Convulsion; Allergic oedema, Hypersensitivity reaction; Pruritus.</td></tr></table> <p>¹Palpable and/or visual swellings, non-inflammatory, non-painful, self-resolving over time</p>	Common (1 to 10 animals / 100 animals treated)	Injection site swelling ¹	Uncommon (1 to 10 animals / 1,000 animals treated)	Decreased appetite; Tiredness; Hyperaemic mucous membranes.	Rare (1 to 10 animals / 10 000 animals treated)	Emesis, Diarrhoea.	Very rare (<1 animal / 10 000 animals treated, including isolated reports)	Muscle tremor, Ataxia, Convulsion; Allergic oedema, Hypersensitivity reaction; Pruritus.
Common (1 to 10 animals / 100 animals treated)	Injection site swelling ¹									
Uncommon (1 to 10 animals / 1,000 animals treated)	Decreased appetite; Tiredness; Hyperaemic mucous membranes.									
Rare (1 to 10 animals / 10 000 animals treated)	Emesis, Diarrhoea.									
Very rare (<1 animal / 10 000 animals treated, including isolated reports)	Muscle tremor, Ataxia, Convulsion; Allergic oedema, Hypersensitivity reaction; Pruritus.									

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		Section 7 of PL for Bravecto 150 mg/ml powder and solvent for suspension for injection for dogs:	
		Common (1 to 10 animals / 100 animals treated):	Injection site swelling ¹
		Uncommon (1 to 10 animals / 1 000 animals treated):	Decreased appetite, Tiredness, Hyperaemic mucous membranes.
		Rare (1 to 10 animals / 10 000 animals treated):	Emesis (vomiting), Diarrhoea.
		Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Muscle tremor, Ataxia (Incoordination), Convulsion, Allergic oedema (swelling), Hypersensitivity reaction, Pruritus (itching).
		¹ Palpable and/or visual swellings, non-inflammatory, non-painful, self-resolving over time	
Coxevac (Coxiella burnetii vaccine (inactivated)) New	10-12 February 2026	Section 3.5 of SPC for COXEVAC suspension for injection for cattle, goats and sheep <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. 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.	
		Section 3.6 of SPC and Section 7 of PL for COXEVAC suspension for injection for cattle, goats and sheep <u>Cattle:</u>	
		Very common (>1 animal / 10 animals treated):	Injection site swelling*
		Rare	Lethargy, Hyperthermia, Anorexia Milk production decrease**

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		<div>(1 to 10 animals / 10,000 animals treated):</div> <div>* Palpable, of 9 to 10 cm diameter maximum, which may last for 17 days, reduces gradually and disappears without need for treatment. ** 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.</div> <div><u>Goats:</u></div> <table><tr><td>Very common (>1 animal / 10 animals treated):</td><td>Injection site swelling* Hyperthermia**</td></tr><tr><td>Common (1 to 10 animals / 100 animals treated):</td><td>Milk production decrease***</td></tr><tr><td>Uncommon (1 to 10 animals / 1,000 animals treated):</td><td>Lethargy, Malaise, Anorexia</td></tr><tr><td>Rare (1 to 10 animals / 10,000 animals treated):</td><td>Diarrhoea</td></tr></table> <div>* Palpable, of 3 to 4 cm diameter maximum, which may last for 14 days, reduces and disappears without need for treatment. ** For 4 days post-vaccination. *** 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.</div> <div><u>Sheep:</u></div> <table><tr><td>Very common (>1 animal / 10 animals treated):</td><td>Injection site inflammation, application site thickening*</td></tr></table>	Very common (>1 animal / 10 animals treated):	Injection site swelling* Hyperthermia**	Common (1 to 10 animals / 100 animals treated):	Milk production decrease***	Uncommon (1 to 10 animals / 1,000 animals treated):	Lethargy, Malaise, Anorexia	Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea	Very common (>1 animal / 10 animals treated):	Injection site inflammation, application site thickening*	
Very common (>1 animal / 10 animals treated):	Injection site swelling* Hyperthermia**												
Common (1 to 10 animals / 100 animals treated):	Milk production decrease***												
Uncommon (1 to 10 animals / 1,000 animals treated):	Lethargy, Malaise, Anorexia												
Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea												
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 Milk production decrease**</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>** 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.</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>Section 3.7 of SPC for COXEVAC suspension for injection for cattle, goats and sheep</p> <p>Pregnancy and lactation:</p> <p><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.</p> <p>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.</p> <p>Section 6 of PL for COXEVAC suspension for injection for cattle, goats and sheep</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>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.</p> <p><u>Pregnancy and lactation:</u></p> <p><u>Cattle and goats:</u></p> <p>The safety of the veterinary medicinal product has not been established during pregnancy.</p> <p>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.</p> <p>The vaccine can be used during lactation.</p>							
Versican Plus DHPPI/L4 (Canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine (inactivated)) New	10-12 February 2026	Section 3.6 of SPC and Section 7 of PL for Versican Plus DHPPI/L4 lyophilisate and suspension for suspension for injection for dogs: Dogs: <table><tr><td>Common (1 to 10 animals / 100 animals treated):</td><td>Injection site swelling¹</td></tr><tr><td>Rare (1 to 10 animals / 10,000 animals treated):</td><td>Injection site lump, Injection site mass, Injection site nodule Hypersensitivity reaction² (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting) Anorexia, Decreased activity</td></tr><tr><td>Very rare</td><td>Hyperthermia, Lethargy, Malaise</td></tr></table>		Common (1 to 10 animals / 100 animals treated):	Injection site swelling ¹	Rare (1 to 10 animals / 10,000 animals treated):	Injection site lump, Injection site mass, Injection site nodule Hypersensitivity reaction ² (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting) Anorexia, Decreased activity	Very rare	Hyperthermia, Lethargy, Malaise
Common (1 to 10 animals / 100 animals treated):	Injection site swelling ¹								
Rare (1 to 10 animals / 10,000 animals treated):	Injection site lump, Injection site mass, Injection site nodule Hypersensitivity reaction ² (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting) Anorexia, Decreased activity								
Very rare	Hyperthermia, Lethargy, Malaise								

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		(<1 animal / 10,000 animals treated, including isolated reports):	Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthrititis
Versican Plus Pi/L4 (Canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine (inactivated)) New	10-12 February 2026	Section 3.6 of SPC and Section 7 of PL for Versican Plus Pi/L4 lyophilisate and suspension for dogs: Dogs:	
		Common (1 to 10 animals / 100 animals treated):	Injection site swelling ¹
		Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction ² (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting) Anorexia, Decreased activity
		Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site lump, Injection site mass, Injection site nodule Hyperthermia, Lethargy, Malaise Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthrititis
Versican Plus Pi/L4R (Canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine and rabies vaccine (inactivated)) New	10-12 February 2026	Section 3.6 of SPC and Section 7 of PL for Versican Plus Pi/L4R lyophilisate and suspension for dogs: Dogs:	
		Common (1 to 10 animals / 100 animals treated):	Injection site swelling ¹
		Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction ² (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting) Anorexia, Decreased activity

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		Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site lump, Injection site mass, Injection site nodule Hyperthermia, Lethargy, Malaise Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthritis
Versican Plus L4 (Canine leptospirosis vaccine (inactivated)) New	10-12 February 2026	Section 3.6 of SPC and Section 7 of PL for Versican Plus L4 lyophilisate and suspension for suspension for injection for dogs: Dogs:	
		Common (1 to 10 animals / 100 animals treated):	Injection site swelling ¹
		Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction ² (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting) Anorexia, Decreased activity
		Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site lump, Injection site mass, Injection site nodule Hyperthermia, Lethargy, Malaise Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthritis
Versican Plus DHPPI/L4R (Canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus vaccine (live) and canine leptospirosis and	10-12 February 2026	Section 3.6 of SPC and Section 7 of PL for Versican Plus DHPPI/L4R lyophilisate and suspension for suspension for injection for dogs: Dogs:	
		Common (1 to 10 animals / 100 animals treated):	Injection site swelling ¹

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rabies vaccine (inactivated)) New		Rare (1 to 10 animals / 10 ,000 animals treated):	Hypersensitivity reaction ² (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting) Anorexia, Decreased activity
		Very rare (<1 animal / 10 ,000 animals treated, including isolated reports):	Injection site lump, Injection site mass, Injection site nodule Hyperthermia, Lethargy, Malaise Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthritis
Yurvac RHD (rabbit haemorrhagic disease and RHDV2 vaccine (recombinant)) New	10-12 February 2026	Section 3.6 of SPC and Section 7 of PL for YURVAC RHD: Rabbits, including pet (dwarf) rabbits:	
		Very common (> 1 animal / 10 animals treated):	Elevated temperature ¹ Injection site inflammation ²
		Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Anorexia ³ , Lethargy³ Intestinal stasis ³ Lameness³
		¹ The highest individual rectal temperature increase was Up to 1.15 °C which returned returning to normal values within 24 hours later . ² Inflammation (< 2 cm) at the injection may can be observed. These local reactions gradually reduce and disappear without need for treatment. ³ Transient.	