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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](#)).



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 border="1" data-bbox="743 859 1949 1240"> <tbody> <tr> <td data-bbox="743 859 1343 938">Common (1 to 10 animals / 100 animals treated)</td><td data-bbox="1343 859 1949 938">Injection site swelling¹</td></tr> <tr> <td data-bbox="743 938 1343 1049">Uncommon (1 to 10 animals / 1,000 animals treated)</td><td data-bbox="1343 938 1949 1049">Decreased appetite; Tiredness; Hyperaemic mucous membranes.</td></tr> <tr> <td data-bbox="743 1049 1343 1129">Rare (1 to 10 animals / 10 000 animals treated)</td><td data-bbox="1343 1049 1949 1129">Emesis, Diarrhoea.</td></tr> <tr> <td data-bbox="743 1129 1343 1240">Very rare (<1 animal / 10 000 animals treated, including isolated reports)</td><td data-bbox="1343 1129 1949 1240">Muscle tremor, Ataxia, Convulsion; Allergic oedema, Hypersensitivity reaction; Pruritus.</td></tr> </tbody> </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.									
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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)								
		<p>Section 7 of PL for Bravecto 150 mg/ml powder and solvent for suspension for injection for dogs:</p> <table border="1" data-bbox="747 366 1978 747"> <tr> <td data-bbox="747 366 1185 485">Common (1 to 10 animals / 100 animals treated):</td><td data-bbox="1185 366 1978 485">Injection site swelling¹</td></tr> <tr> <td data-bbox="747 485 1185 565">Uncommon (1 to 10 animals / 1 000 animals treated):</td><td data-bbox="1185 485 1978 565">Decreased appetite, Tiredness, Hyperaemic mucous membranes.</td></tr> <tr> <td data-bbox="747 565 1185 644">Rare (1 to 10 animals / 10 000 animals treated):</td><td data-bbox="1185 565 1978 644">Emesis (vomiting), Diarrhoea.</td></tr> <tr> <td data-bbox="747 644 1185 747">Very rare (<1 animal / 10 000 animals treated, including isolated reports):</td><td data-bbox="1185 644 1978 747">Muscle tremor, Ataxia (Incoordination), Convulsion, Allergic oedema (swelling), Hypersensitivity reaction, Pruritus (itching).</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 (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).
Common (1 to 10 animals / 100 animals treated):	Injection site swelling ¹									
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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).									
Coxevac (Coxiella burnetii vaccine (inactivated)) New	10-12 February 2026	<p>Section 3.5 of SPC 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>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>Section 3.6 of SPC and Section 7 of PL for COXEVAC suspension for injection for cattle, goats and sheep</p> <p><u>Cattle:</u></p> <table border="1" data-bbox="747 1240 1949 1395"> <tr> <td data-bbox="747 1240 1185 1319">Very common (>1 animal / 10 animals treated):</td><td data-bbox="1185 1240 1949 1319">Injection site swelling*</td></tr> <tr> <td data-bbox="747 1319 1185 1395">Rare</td><td data-bbox="1185 1319 1949 1395">Lethargy, Hyperthermia, Anorexia Milk production decrease**</td></tr> </table>	Very common (>1 animal / 10 animals treated):	Injection site swelling*	Rare	Lethargy, Hyperthermia, Anorexia Milk production decrease**				
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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)												
		<p>(1 to 10 animals / 10,000 animals treated):</p>	<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>** 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>Goats:</u></p> <table border="1" data-bbox="743 600 1949 1013"> <tbody> <tr> <td data-bbox="743 600 1215 679">Very common (>1 animal / 10 animals treated):</td><td data-bbox="1215 600 1949 679">Injection site swelling* Hyperthermia**</td></tr> <tr> <td data-bbox="743 679 1215 795">Common (1 to 10 animals / 100 animals treated):</td><td data-bbox="1215 679 1949 795">Milk production decrease***</td></tr> <tr> <td data-bbox="743 795 1215 906">Uncommon (1 to 10 animals / 1,000 animals treated):</td><td data-bbox="1215 795 1949 906">Lethargy, Malaise, Anorexia</td></tr> <tr> <td data-bbox="743 906 1215 1013">Rare (1 to 10 animals / 10,000 animals treated):</td><td data-bbox="1215 906 1949 1013">Diarrhoea</td></tr> </tbody> </table> <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>*** 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>Sheep:</u></p> <table border="1" data-bbox="743 1314 1949 1397"> <tbody> <tr> <td data-bbox="743 1314 1215 1397">Very common (>1 animal / 10 animals treated):</td><td data-bbox="1215 1314 1949 1397">Injection site inflammation, application site thickening*</td></tr> </tbody> </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**													
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Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea													
Very common (>1 animal / 10 animals treated):	Injection site inflammation, application site thickening*													

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)	
		<p>Rare (1 to 10 animals / 10,000 animals treated):</p>	<p>Lethargy, Hyperthermia, Anorexia Milk production decrease**</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.

**** 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.**

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.

Section 3.7 of SPC for COXEVAC suspension for injection for cattle, goats and sheep

Pregnancy and lactation:

Cattle and goats:

The safety of the veterinary medicinal product has not been established during pregnancy.

The vaccine can be used during lactation.

~~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.~~

Section 6 of PL for COXEVAC suspension for injection for cattle, goats and sheep

Special precautions for safe use in the target species:

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.

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)						
		<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	<p>Section 3.6 of SPC and Section 7 of PL for Versican Plus DHPPi/L4 lyophilisate and suspension for suspension for injection for dogs:</p> <p>Dogs:</p> <table border="1" data-bbox="747 1044 1933 1383"> <tr> <td data-bbox="747 1044 1253 1124">Common (1 to 10 animals / 100 animals treated):</td><td data-bbox="1253 1044 1933 1124">Injection site swelling¹</td></tr> <tr> <td data-bbox="747 1124 1253 1319">Rare (1 to 10 animals / 10,000 animals treated):</td><td data-bbox="1253 1124 1933 1319"> 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 data-bbox="747 1319 1253 1383">Very rare</td><td data-bbox="1253 1319 1933 1383">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
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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)	
		(<1 animal / 10,000 animals treated, including isolated reports):	Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthritis
Versican Plus Pi/L4 (Canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine (inactivated)) New	10-12 February 2026	<p>Section 3.6 of SPC and Section 7 of PL for Versican Plus Pi/L4 lyophilisate and suspension for suspension for injection for dogs:</p> <p>Dogs:</p>	
		Common (1 to 10 animals / 100 animals treated):	Injection site swelling ¹
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Versican Plus Pi/L4R (Canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine and rabies vaccine (inactivated)) New	10-12 February 2026	<p>Section 3.6 of SPC and Section 7 of PL for Versican Plus Pi/L4R lyophilisate and suspension for suspension for injection for dogs:</p> <p>Dogs:</p>	
		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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		<p>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</p> <p>Injection site lump, Injection site mass, Injection site nodule Hyperthermia, Lethargy, Malaise Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthritis</p>						
Versican Plus L4 (Canine leptospirosis vaccine (inactivated)) New	10-12 February 2026	<p>Section 3.6 of SPC and Section 7 of PL for Versican Plus L4 lyophilisate and suspension for suspension for injection for dogs:</p> <p>Dogs:</p> <table border="1"> <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>Hypersensitivity reaction² (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting) Anorexia, Decreased activity</td></tr> <tr> <td>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</td><td>Injection site lump, Injection site mass, Injection site nodule Hyperthermia, Lethargy, Malaise Immune mediated haemolytic anaemia, Immune mediated haemolytic thrombocytopenia, Immune mediated polyarthritis</td></tr> </table>	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
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Versican Plus DHPPi/L4R (Canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus vaccine (live) and canine leptospirosis and	10-12 February 2026	<p>Section 3.6 of SPC and Section 7 of PL for Versican Plus DHPPi/L4R lyophilisate and suspension for suspension for injection for dogs:</p> <p>Dogs:</p> <table border="1"> <tr> <td>Common (1 to 10 animals / 100 animals treated):</td><td>Injection site swelling¹</td></tr> </table>	Common (1 to 10 animals / 100 animals treated):	Injection site swelling ¹				
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rabies vaccine (inactivated))		Rare (1 to 10 animals / 10 ,000 animals treated):	Hypersensitivity reaction ² (anaphylaxis, angioedema, circulatory shock, collapse, diarrhoea, dyspnoea, vomiting) Anorexia, Decreased activity
New		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))		Section 3.6 of SPC and Section 7 of PL for YURVAC RHD: Rabbits, including pet (dwarf) rabbits:	
New			
	10-12 February 2026		
		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):	Anorexia³, Lethargy³ Intestinal stasis ³ Lameness³