15 May 2025
EMA/CVMP/PhVWP/101663/2025
Veterinary Medicines Division

Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2025

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 **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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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~~)
Divence Penta (bovine viral diarrhoea (subunit), bovine parainfluenza 3 virus (inactivated), bovine respiratory syncytial virus and bovine herpesvirus type 1 (live) vaccine)	**13-15 May 2025**	**Section 3.6 of SPC and Section 7 of PL for Divence Penta:** Target species: Cattle *Very common (>1 animal / 10 animals treated, including isolated reports):* Injection site inflammation[1], elevated temperature[2] *Uncommon (1 to 10 animals / 1,000 animals treated, including isolated reports):* Anaphylactic-type reaction[3]. **Milk production decrease[4].** **Reduced food intake[4], Decreased activity[4].** [1] A slight to moderate transient injection site inflammation (up to 14 cm of diameter) may be observed, which rapidly decreases in diameter within 2 days and subsides within 2 weeks without treatment. [2] An elevated temperature (mean increase 1.7 ºC, in individual animals up to 2.4 ºC) may occur after vaccination. This increase subsides spontaneously within 3 days. [3] In cases of anaphylactic-type reactions, an appropriate symptomatic treatment should be administered. **[4] Observed in dairy cows, mostly after application of primary dose**.
Osurnia (Terbinafine/Florfenicol/ Betamethasone acetate)	**11-13 March 2025**	Section 4.5 of SPC and section 12 of the PL: The veterinary medicinal product may be irritating to eyes. Avoid accidental contact to the dog's eyes. If accidental ocular exposure does occur, the eyes should be flushed thoroughly with water for 10 to 15 minutes. If clinical signs develop, seek veterinary advice. ~~In very rare cases, eye disorders such as keratoconjunctivitis sicca and corneal ulcers have been reported in treated dogs, in absence of eye contact with the product. Although a causal relationship with the veterinary medicinal product was not definitively established, o~~**O**wners should be

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~~)
		recommended to monitor ocular signs (such as squinting, redness and discharge) in the hours and days following the product application, and to promptly consult a veterinarian in case such signs appear. **See section 4.6 [PL: section 6] for details on ocular adverse events in dogs.** <u>Section 4.6 of SPC and section 6 of the PL:</u> Deafness or impaired hearing, usually temporary, have been reported after use in very rare cases in dogs, mainly in elderly animals, in post authorisation experience. Application site reactions (i.e. erythema, pain, pruritus, oedema and ulcer) have been reported in very rare cases, in post authorisation experience. Hypersensitivity reactions including facial oedema, urticaria and shock have been reported in very rare cases, in post authorisation experience. **In very rare cases, eye disorders such as neurogenic keratoconjunctivitis sicca, keratoconjunctivitis sicca, corneal ulcer, blepharospasm, eye redness and ocular discharge have been reported in treated dogs (see also section 4.5 [PL: section 12] – special precautions for use in animals).** **Ataxia, internal ear disorder (mainly head tilt), facial paralysis and nystagmus have been reported in very rare cases in post authorisation experience.**