

Product	Species	Details	Current SPC	Category of deviation	Possible deviation	Comment
Alfaxalone	Dog/Cat	Induction agent prior to inhalational anaesthesia	IV	Administration	IM (particularly in non-cooperative animals or where intravenous access is difficult).	Studies demonstrate the achievement of adequate sedation, good tolerability, and the absence of clinically significant adverse effects. Hoon TMAY, Kat ITW, Pastoske K, Farry T, Goodwin WA. A dose characterization study evaluating the pharmacodynamics and safety of a concentrated alfaxalone solution (4%) as an intramuscular sedative in dogs. J Vet Pharmacol Ther. 2024 May;47(3):157-167. doi: 10.1111/jvp.13423. Epub 2023 Dec 27. PMID: 38151755.
Analgesic (NSAID) treatment – examples: Anil and Metacam	Pigs	Pain	Anil is authorized for 1 day, with the possibility of 2 days of treatment. Metacam is authorized as a single administration, with the statement that "if necessary, an additional dose may be given the following day.	Duration	Pain management in pigs ranges from acute, short-lasting conditions to more prolonged or recurring pain requiring individual clinical assessment of treatment duration	
Buprenorphine (e.g. Buprecare, Bupaq, Buprenodale, Buprelab, Bupredine)	Cat	Analgesia (e.g., post-operative analgesia and acute pain management).	The SPCs describe buprenorphine as a solution for injection and administration is framed as parenteral (e.g., IV/IM), without stating oral transmucosa/buccal administration.	Administration	In feline clinical practice, the transmucosal route is used to facilitate at-home analgesia when repeated injections are not feasible (improved compliance and welfare, reduced handling, and reduced needle-related incidents). Therefore, clinicians may need to deviate from the SPC route to implement an individualized analgesic protocol.	There is evidence and clinical reviews in cats describing the pharmacology and clinical use of buprenorphine via the oral transmucosal route (PK/PD data and clinical experience), supporting its use as a practical alternative to parenteral administration in this species. E.g.: Hedges AR, et al. Pharmacokinetics of buprenorphine following intravenous and buccal administration in cats (and concentration–effect relationship). J Vet Pharmacol Ther. 2014. Robertson SA, et al. PK-PD modeling of buprenorphine in cats: intravenous and oral transmucosal administration. J Vet Pharmacol Ther. 2005;28(5):453-460. doi:10.1111/j.1365-2885.2005.00677.x
Cefapirin / Prednisolone combinations, intramammary use (e.g. Mastiplan LC)	Cattle	Mastitis	One syringe should be infused into each affected quarter via the teat canal, immediately after milking, at 12 hour intervals for 4 consecutive milkings.	Duration	In daily practice, SPC-authorized dose/duration is frequently inadequate to achieve clinical efficacy: it is often necessary to extend the treatment up to 8 consecutive milkings.	
Cytopoint (Lokivetmab) 10 mg solution for injection	Dog	Treatment of pruritus associated with allergic dermatitis in dogs. Treatment of clinical manifestations of atopic dermatitis in dogs.	The recommended minimum dose is 1 mg/kg bodyweight, once a month. The need for repeat or longer-term treatment in dogs with allergic dermatitis should be based on the needs of the individual patient.	Duration	The response to treatment by individual dogs can be very variable, with some requiring repeated treatment more frequently than once monthly.	
Detomidine (e.g. sedomidine, domosedan)	Horses	Sedation and analgesia to facilitate manipulation, premedication prior to anesthesia	80 µg/kg maximal dosage	Dosage	Required dosage is case and procedure-dependent. Higher cumulative dosages (100-200µg/kg) may be necessary for long procedures, standing surgery, premedication). Same for Butorphanol.	
Dexamethasone	FPA	Inflammatory conditions, shock, allergic reactions, parturition-related conditions, supportive therapy	Authorized veterinary medicinal products across countries containing dexamethasone indicate markedly different indications and dosage regimens for the same species. SPCs report dosages ranging from very low anti-inflammatory doses to significantly higher doses for specific indications, with substantial variation in duration and frequency of administration.	Dosage/Duration	In daily clinical practice, dexamethasone is widely used across a range of inflammatory and emergency conditions that are not consistently or comprehensively reflected in individual SPCs. Strict adherence to a single product-specific SPC often does not allow adequate tailoring of dose and treatment duration to the clinical condition and severity.	

Equine Influenza vaccines	Horses	Equine Influenza	SPC saying 12 months interval	Duration	FEI demanding 6 months interval	In the SPC for, for example, the influenza vaccine Equilis prequenza, dosing suggestions are indicated with a recommendation for annual revaccination (12 months) after the basic vaccinations. FEI recommends a maximum interval of 6 months, which puts the vet in a professional dilemma between recommendations and legislation. In the SPC for the influenza vaccine proteqFlu Likewise, dosage suggestions (1st program) with instructions on annual revaccination after primary vaccination. FEI recommends a maximum interval of 6 months, which puts the vet in a professional dilemma between recommendations and legislation. Gildea et al. 2020. Annual booster vaccination and the risk of equine influenza to Thoroughbred racehorses, <i>Equine Vet. J.</i> 52, ss. 509-515.
Florfenicol and NSAID combination (e.g. Zeleris, Resflor)	Cattle	treatment of bovine respiratory disease (BRD) — specifically in cases associated with pyrexia and due to bacterial pathogens such as: Mannheimia haemolytica, Pasteurella multocida, Histophilus somni. In some markets also authorised for treatment of Mycoplasma bovis.	1) Zeleris (1 ml contains 400 mg Florfenicol and 5 mg Meloxicam); it is registered for a single dose: 1 ml/10 kg BW. 2) Resflor (1 ml contains 300 mg Florfenicol and Flunixin 16,5 mg), 2 ml/16 kg BW one shot. Registered for a single dose.	Duration	While normally a single injection is enough, at times, for specific cases, a second dose can be necessary	
Flunixin Meglumine	Horses	Inflammatory disorders	1,1mg/kg IV once daily or 0.25mg/kg q8h	Dosage	1,1mg/kg IV BID (or TID) in case of severe inflammatory disorders/endotoxemia	Also commonly used for anti-endotoxic effect
Flunixin Meglumine	Horses	Foals e.g. acute abdomen surgery	Adjunctive therapy of endotoxemia due to or as a result of post-surgical or medical conditions or diseases that result in impaired blood circulation in the gastrointestinal tract - SPC dose: 0.25 mg flunixin/kg bodyweight every 6-8 hours or 1.1 mg flunixin/kg bodyweight once daily for up to 5 consecutive days.	Dosage	1,65 mg/kg IV for foals + increase of the dose interval to avoid toxicity. Recommended dose in a postoperative acute abdomen foal in this situation is three times a day, not twice as listed in SPC.	Treatment of foals with this NSAID is different from treatment in adult horses. This is because foals have a higher content of water in the body, a larger extracellular fluid compartment, lower serum protein concentrations and a different metabolism of drugs. As a result of scientific studies of the pharmacokinetics of flunixin meglumine, it is recommended that the dose be increased by a factor of up to 1.5 (~ 1.65 mg/kg) and that the dose interval be increased to avoid toxicity (Crisman et al. 1996) Unfortunately, this is not taken into account in the SPC, where only one dose is approved (1.1 mg/kg). In foals, this will lead to underdosing and hence not satisfactory pain relief. Gillen, A. (2024). The Acute Abdomen in the Neonatal Foal. In <i>Equine Neonatal Medicine</i> (eds D.M. Wong and P.A. Wilkins). https://doi-org.ucd.idm.oclc.org/10.1002/9781119617228.ch18 Newborn foals have a different pharmacokinetic profile (Crisman et al. 1996) Crisman et al. 1996. Pharmacokinetics of flunixin meglumine in healthy foals less than twenty-four hours old. <i>Am. J. Vet. Res.</i> (57), ss. 1759-1761.
Glucocorticoids	Horses	Anti-inflammatory and anti-allergic conditions	Many different types of GC exist for different administration methods	Dosage/Duration	In order to avoid unnecessary underdosing and long-term overtreatment, it should be possible to adapt the treatment to the individual, based on the vet's knowledge of the patient. With the current instructions in the SPC, it cannot be done. This can be fatal for the animal.	Pharmacological doses of glucocorticoids have a profound impact on the endogenous glucocorticoid regulation in the animal, as treatment with these substances will suppress both the hypothalamic and pituitary hormone production through negative feedback. To make sure that the HPA-axis (hypothalamus -pituitary- adrenal axis) regains its normal function after treatment is finished, it is necessary for the patient to slowly be weaned off the treatment with exogenous glucocorticoids. If this is not done, the patient can develop severe signs of glucocorticoid withdrawal symptoms, like depression, exercise intolerance, weight loss, diarrhea, and behavioural changes and iatrogenous cushings disease. Another potential severe problem with the use of glucocorticoids, is that the approved dose for horses of 1 mg/kg (in the SPC), can lead to severe life threatening disease in horses predisposed to the disease laminitis. If the dose is not lowered for these horses, the risk of developing laminitis is markedly increased! With these drugs it is essential that the dose can be adjusted for each patient according to any potential underlying disease. (Adams 2001, cuming et al 2018). Therefore the dose needs to be adapted to the individual patient.

Hormonal medicinal products for reproductive management	Small ruminants	Oestrus synchronisation protocols	SPCs authorise only standard synchronisation protocols, typically based on long-term intravaginal devices and fixed treatment schedules.	Duration	In small ruminant practice, short-term synchronisation protocols are widely used and considered more effective, practical and welfare-friendly. However, these protocols are not included in SPCs, preventing their routine application despite demonstrated efficacy	Scientific literature and international reproductive management guidelines support the use of short-term synchronisation protocols in small ruminants, showing comparable or improved reproductive outcomes compared to long-term protocols, with reduced treatment duration and handling.
Imidocarp	Dog	Babesiosis	0.25 ml/10 kg BW (2.125 mg Imidocarb/kg BW) Dog:	Dosage	Higher doses needed according to ESCAAP	The ESCCAP recommendation for the treatment of canine babesiosis is 5-6mg imidocarb per kg body weight of the dog twice at intervals of 14 days.
Medetomidine (e.g. domitor)	Dog/Cat	Sedation, premedication prior to anesthesia	- to calm: 10 - 40 mcg/kg - sedation + analgesia: 40 - 80 mcg/kg anesth (< 1 h): 20 - 40 mcg/kg + 8 - 10 mg/kg ketamine 50 - 60 mcg/kg + 2 - 4 mg/kg ketamine prolong anesth met 2 - 4 mg/kg ketamine - anesth (> 1 h): dosis anestheticum reduce with 30 - 50 % 10 - 40 mcg/kg + halothaan 10 mcg/kg + pentobarbital Cat: to calm/sedate: 20 - 150 mcg/kg	dosage	Evidence from published studies indicates that doses are too high. Doses as low as 5 µg/kg may be sufficient to achieve adequate sedation.	Schöndorfer B, Vogl C, Eberspächer-Schweda E. Sedative effects and changes in cardiac rhythm with intravenous premedication of medetomidine, butorphanol and ketamine in dogs. <i>Vet Anaesth Analg.</i> 2023 Mar;50(2):136-145. doi: 10.1016/j.vaa.2022.12.006. Epub 2022 Dec 28. PMID: 36754695.
Meloxicam (e.g. Metacam)	Horses	Alleviation of inflammation and relief of pain in both acute and chronic musculoskeletal disorders	0.6mg/kg SID PO	Dosage	0.6mg/kg BID PO in foals	Treatment of foals with this NSAID is different from treatment of adult horses. This is because foals have a higher content of water in the body, a larger extracellular fluid compartment, lower serum protein concentrations and a different metabolism of drugs. As a result of scientific studies of the pharmacokinetics of meloxicam, it is recommended to use a dosage of 0.6 mg/kg PO twice daily for foals under 7 weeks of age (Raidal et al. 2013). Unfortunately, this is not taken into account in SPC, where the dose is 0.6 mg/kg once daily. In foals, this will lead to underdosing and hence not satisfactory pain relief.
Meloxicam (e.g. Metacam, Loxicom, Meloxidyl, Meloxoral, Inlacam, Rheumocam)	Cat	Chronic musculoskeletal disorders (e.g., chronic pain consistent with osteoarthritis), when long-term NSAID therapy is considered with patient selection and monitoring.	Some SPCs include a maintenance dose (e.g., 0.05 mg/kg q24h) and an operational statement such as stopping if there is no improvement after 14 days.	dosage	For chronic pain, consensus guidance recommends individualizing and using the lowest effective dose, with potential dose reduction (e.g., down to 50% or even 25% of a "standard" dose and/or adjusted frequency) alongside screening and monitoring. This may require deviation from a flat SPC regimen to balance sustained efficacy with risk minimization.	2024 ISFM/AAFP consensus guidelines on long-term NSAID use in cats: lowest effective dose, screening and monitoring framework. Earlier expert guidance (Sparkes et al.) discussing long-term NSAID use in cats and published experience with lower-than-label dosing in some settings.

Omeprazole buffered oral paste (e.g. Gastrogard)	Horses	Treatment of EGUS (Equine Gastric Ulcer Syndrome) = Equine Squamous Gastric Disease (ESGD) and Equine Glandular Gastric Disease (EGGD)	4mg of omeprazole/kg SID PO during 28 days, then 1mg/kg SID PO during 28 days	Dosage	Dose increased to 4 mg of omeprazole/kg BID for EGGD	The drug is used in various formulations to combat peptic ulcers, both in the non-glandular part of the stomach and in the glandular part, as well as at the transition to the small intestine, called pylorus. However, processing of the SPCs' declarations is quite problematic. The current dosage recommendations do not take into account the latest evidence, which describes highly variable acid suppression at the indicated dose of 4 mg/kg administered once daily. Studies have shown a very variable bioavailability of the different omeprazole products, depending on whether the horse has eaten or not. This can affect the effect of the medicine in a negative direction (Sykes 2019). If the current dosing recommendations regarding frequency of dosing in SPC are followed strictly, somewhere between 15-30% of the horses will be undertreated, depending on where their stomach ulcer is located. This applies especially to horses with ulcers in the glandular part of the stomach (Sykes et al. 2014). Individual response to gastric ulcer treatment is therefore a far more decisive factor for correct medical management of the horse than adhering to a generic "one size fits all" treatment for all horses with gastric ulcers cf. SPC. The duration of the treatment the horse must have in order to achieve healing is specified in the SPC as 28 days. However, this can vary enormously between patients. Studies have shown that treatment for 14 days in some patients can be sufficient (St. blank 2021), which is why dosing for 28 days in those horses will lead to markedly unnecessary overtreatment.
Paracetamol - Pardale V	Dog	pain relief	SPC dose 33mg/kg po q8h	Dosage	Recommended dose 10-15mg/kg.	While licensed veterinary products like Pardale-V have approved dosing regimens, scientific papers often focus on pharmacokinetics, plasma levels and analgesic efficacy rather than strict dose recommendations. Therapeutic doses in the literature span roughly 10–20 mg/kg for acetaminophen (often repeated every 8h in research protocols), though formulations and combinations differ; always integrate clinical judgement and product licences when applying to patients. Fadel C, Sartini I, Giorgi M. Paracetamol: A Focus on Dogs. Am J Anim Vet Sci. 2021;16(4):247–262. doi:10.3844/ajavsp.2021.247.26 Pacheco M, et al. Comparing paracetamol/codeine and meloxicam for postoperative analgesia in dogs. Vet Rec. 2020;187(8):e61. doi:10.1136/vr.10548
Phenylbutazone (e.g. equipalazone)	Horses	Chronic laminitis	In some countries, the only indication is for chronic laminitis, with an initial dose of 4,4mg/kg BID on the first day, then degressing dose until the end of the treatment	Dosage	Commonly used for other indications such as trauma, post surgical care, osteo-articular infections, for which the initial dose of 4mg/kg can be required more than 24 hours	Evidence from controlled experimental and clinical studies support the use of phenylbutazone its analgesic effects in equine lameness and postoperative pain. Jacobs CC, Schnabel LV, Mclwraith CW, Blikstager AT. Non-steroidal anti-inflammatory drugs in equine orthopaedics. Equine Vet J. 2022 Jul;54(4):636-648. doi: 10.1111/evj.13561. Epub 2022 Feb 10. PMID: 35076950; PMCID: PMC9304133. Johnson CB, Taylor PM, Young SS, Brearley JC. Postoperative analgesia using phenylbutazone, flunixin or carprofen in horses. Vet Rec. 1993 Oct 2;133(14):336-8. doi: 10.1136/vr.133.14.336. PMID: 8236675.
Phenylpropanolamine	Dog	Treatment of urinary incontinence	Dose of 1 mg/kg every 8 hours	Dosage	International clinical guidelines recommend a higher dose of 2 mg/kg every 8–12 hours.	Kendall A, Byron JK, Westropp JL, Coates JR, Vaden S, Adin C, Oetelaar G, Bartges JW, Foster JD, Adams LG, Olby N, Berent A. ACVIM consensus statement on diagnosis and management of urinary incontinence in dogs. J Vet Intern Med. 2024 Mar-Apr;38(2):878-903. doi: 10.1111/jvim.16975. Epub 2024 Jan 13. PMID: 38217372; PMCID: PMC10937496.
Prednisolone (e.g. Hedyton)	Dog/Cat	Inflammatory and immune-mediated diseases	Recommended dose for immunosuppression for dogs and cats is 0.5–2 mg/kg/day or 1–2 mg/kg/day.	Dosage	International guidelines for the management of immune-mediated diseases recommend doses of 2–4 mg/kg/day	Dosage and length has to be adapted to patient and severity. LeVine DN, Goggs R, Kohn B, Mackin AJ, Kidd L, Garden OA, Brooks MB, Eldermire ERB, Abrams-Ogg A, Appleman EH, Archer TM, Bianco D, Blois SL, Brainard BM, Callan MB, Fellman CL, Haines JM, Hale AS, Huang AA, Lucy JM, O'Marra SK, Rozanski EA, Thomason JM, Walton JE, Wilson HE. ACVIM consensus statement on the treatment of immune thrombocytopenia in dogs and cats. J Vet Intern Med. 2024 Jul-Aug;38(4):1982-2007. doi: 10.1111/jvim.17079. Epub 2024 May 23. PMID: 38779941; PMCID: PMC11256181.

Syvazul BTV 3 suspension for injection	Cattle/Sheep	To stimulate active immunity of sheep and cattle against bluetongue virus serotype 3	Sheep: Primary vaccination: administer a single 2 ml dose.	Dosage	Under field conditions, a second dose of the vaccine has been administered to improve efficacy.	FVE acknowledges the rapid efforts made by MAHs to make this emergency vaccine available. Based on experience in the Netherlands, the adequacy of a single dose for primary vaccination of sheep was further evaluated, and the Dutch Ministry issued a decision to deviate from the SPC. The rationale for this deviation for Syvazul BTV3 has been published. Adaptations should be possible for these emergency vaccines without unnecessary admin.
Telmisartan	Cat	Reduction of proteinuria associated with chronic kidney disease (CKD) in cats	SPC specifies a dose of 1 mg/kg	Dosage	Clinical guidelines recommend a dose of 2 mg/kg in cats.	IRIS guidelines: treatment recommendations for CKD in cats (2023)
Trilostane (e.g. Vetoryl, Trilotab)	Dog	Treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease and syndrome).	Recommended dose of 2 mg/kg administered once daily.	Dosage	Clinical guidelines based on published evidence recommend lower divided doses: 0.5–1 mg/kg every 12 hours for pituitary-dependent hyperadrenocorticism and 0.2–0.5 mg/kg every 12 hours for adrenal-dependent hyperadrenocorticism.	If the drug is actually administered at this dose, an Addisonian crisis often occurs. Bugbee A, Rucinsky R, Cazabon S, Kvitko-White H, Lathan P, Nichelason A, Rudolph L. 2023 AAHA Selected Endocrinopathies of Dogs and Cats Guidelines. J Am Anim Hosp Assoc. 2023 May 1;59(3):113-135. doi: 10.5326/JAAHA-MS-7368. PMID: 37167252. Vaughan MA et al., 2008, JAVMA: Demonstrated effectiveness of low-dose trilostane and reduction of effect within 8–9 hours in some dogs, supporting BID dosing. Cho KD et al., 2013, Journal of Veterinary Internal Medicine: Low-dose twice-daily trilostane effective for pituitary-dependent hyperadrenocorticism with potential safety advantages.
Vaccines (multiple brands e.g. MSD, Virbac, Boehringer Ingelheim, Zoetis for feline herpesvirus, calicivirus, FeLV, parvovirus)	Dog/Cat	Prevention of infectious diseases	Annual revaccination	Duration	Every 3 years	Duration of immunity is longer than what is often provided in SPC. Antigen titer testing can be done. Many vaccine guidelines advise for longer intervals between vaccines based on risk assessment: ABCD guidelines on vaccination / WSAVA guidelines on vaccination / AAFP/FelVMA guidelines on vaccination.
Vitamin B1 (thiamine; e.g. Corebral®, NutraB®)	Cattle/Calves	Calves: Cerebrocortical necrosis	NutraB: 10 ml IM or IV, 2 injections with 24 hr interval Corebral: 1 mL per 10 kg body weight once daily, normally one injection, but in severe cases, dose may be doubled	Dosage	Dose often insufficient. For acute CCN, ~2.5–5 mL per 50 kg BW of a thiamine injectable, repeated every ~3 hours for up to 5 doses in severe CCN clinical cases	Higher doses are required in clinical cases to achieve neurological recovery and prevent irreversible damage. This is already recognised in some SPCs but not others. Widely accepted treatment protocols and teaching references in food-animal medicine.