

Cascade use



Guide for veterinarians

if NO authorised veterinary
medicine is available

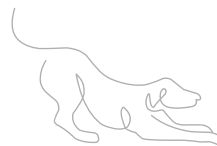
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Federation
of Veterinarians
of Europe

For any questions or comments,
please feel free to contact us.

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Interpretation recommendations aligning Art 106.1 with 112-114

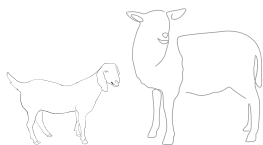
The cascade use aims at addressing specific animal health/welfare needs **where a suitable veterinary medicinal product is not available** ("unmet clinical need"). However, cascade use is not aimed at addressing widespread lack of efficacy or safety concerns from the use of a veterinary medicinal product in accordance authorisation (i.e. no systematic deviation from the allowed that is unrelated to specific health conditions of individual animals).

The cascade use includes cases where **there is no veterinary medicinal product authorised** to treat the relevant condition or target species, or when that **veterinary medicinal product is not available**. It also covers cases where a **specific clinical setting is not addressed** under the terms of the marketing authorisation.

Individual responses may vary to treatment. If, after initiating treatment, the treated animal does not adequately respond or if it experiences adverse events, cascade use is justified. **Lack of efficacy or adverse events should be reported.**

Cascade use **may also be necessary to comply with legal/regulatory requirements.**

Other clinical circumstances exist where the cascade use may be justified, **if no suitable veterinary medicinal product is authorised/available** & the vet considers that such use is in the **best interest of the animal.**



Scenarios of unmet clinical need	Cascade use allowed?
Specific animal subset not covered by the terms of the marketing authorisation (e.g. pregnant animal, new born, very old animal).	Yes
Underlying health conditions of the animal are not covered by the terms of the marketing authorisation (e.g. renal or liver impairment, gastrointestinal ulcer, hypersensitivity).	Yes
Concomitant use with other VMPs, not addressed in marketing authorisation.	Yes
Animal does not adequately respond to treatment (lack of efficacy).	Yes. The event should be reported.
Treated animal suffers from adverse events which require clinical response.	Yes. The event should be reported.
The specific clinical setting is contraindicated.	Only if an alternative VMP covering the clinical needs of the animal is not available.
More severe condition than the one foreseen in the marketing authorisation (e.g. advanced staged disease state).	Only if an alternative VMP covering a more severe condition is not available.
Route of administration not covered by the marketing authorisation is necessary to address the specific clinical need of the animal.	Only if an alternative VMP with the required route of administration is not available.
A specific vaccination schedule not covered by the marketing authorisation is required to comply with legal/regulatory requirements.	Only if an alternative VMP with the required route of administration is not available.

Is there an authorised veterinary medicine for this species and indication?



Under exceptional circumstances and in particular to avoid unacceptable suffering the veterinarian is allowed to use the Cascade. Is this the case?

NO

YES

Is there a veterinary medicine authorised for another species /condition in your or another Member State?

YES

Use authorised veterinary medicine*

NO

YES

Use this authorised veterinary medicine*

YES

Use this authorised medicine*

NO

Is it possible to extemporaneously prepare a product?

YES

Prepare extemporaneously*

NO

Is there a veterinary medicine product authorised in a third country for the same species and same indication?

YES

Use this authorised veterinary medicine **

NO

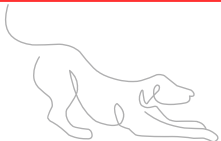
NO

No treatment with a medicinal product possible

For details on specific precautions and veterinarian responsibilities, please refer to pages 10-11



*Restrictions to the use of antimicrobials may apply



**Does not apply to immunologicals (vaccines)

Is there an authorised veterinary medicine for this species and indication?

NO

YES

Under exceptional circumstances and in particular to avoid unacceptable suffering the veterinarian is allowed to use the Cascade. Is this the case?

YES

Is there a veterinary medicine authorised for another **food-producing** species /condition in your or in another Member State?

YES

Use this authorised veterinary medicine*

Use this authorised veterinary medicine*

NO

Is there a veterinary medicine authorised in the relevant Member State for use in a **non-food-producing** animal species for the same indication?

YES

Use this authorised veterinary medicine*

NO

Is there a medicinal product for human use authorised in your country or another EU Member State?

YES

Use this authorised product*

NO

Is it possible to extemporaneously prepare a product?

YES

Prepare extemporaneously*

YES

Use this authorised veterinary medicine **

NO

Is there a veterinary medicine product authorised in a third country for the same species and same indication?

YES

No treatment with a medicinal product possible

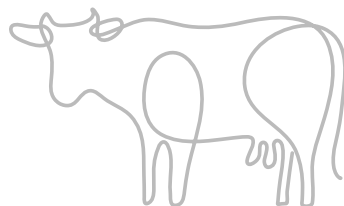
NO



For details on specific precautions, veterinary responsibilities, and withdrawal periods, please refer to pages 10-11.



*Restrictions to the use of antimicrobials and concerning maximum residue limit (MRL) status may apply



**Does not apply to immunologicals (vaccines)



Is there an authorised veterinary medicine for this species and indication?

NO

YES

Under exceptional circumstances and in particular to avoid unacceptable suffering the veterinarian is allowed to use the Cascade. Is this the case?

YES

Is there a veterinary medicine authorised for same/another **aquatic species** /condition in your or another Member State?

YES

Use this authorised veterinary medicine*

Use this authorised veterinary medicine*

NO

Is there a veterinary medicine product authorised for use in **food-producing** terrestrial species in your or in another Member State?

YES

Use this authorised veterinary medicine*

NO

Is there a medicinal product for human use authorised in your country or another EU Member State?

YES

Use this authorised product*

NO

Is it possible to extemporaneously prepare a product?

YES

Prepare extemporaneously*

YES

Use this authorised veterinary medicine **

NO

Is there a veterinary medicine product authorised in a third country for the same species and same indication?

NO

No treatment with a medicinal product possible

For details on specific precautions, veterinary responsibilities, and withdrawal periods, please refer to pages 10-11.

! Restrictions to the use of antimicrobials and concerning maximum residue limit (MRL) status may apply

Please note that a list under Article 114(3) ('Aquatic List') is currently being developed. Changes may occur once the list is finalized and becomes available



**Does not apply to immunologicals (vaccines)

Is there an authorised product for this species and indication?

YES

Use authorised
veterinary medicine*

NO

Under exceptional circumstances and in particular to avoid unacceptable suffering the veterinarian is allowed to use the Cascade. Is this the case?

YES

Is the equid's passport declaring the animal as not intended for slaughter for human consumption?

YES

Use the Cascade as
for companion
animals (page 2-3)

NO

Can you use the Cascade
as for **food-producing**
terrestrial species?

YES

Use the Cascade for **food-producing** terrestrial species and specify a withdrawal period accordingly (page 4-5)

NO

Can you use a substance
from the list of essential
substances for equids?

YES

Use a substance from the list and specify a withdrawal period of 6 months (page 12-13)

NO

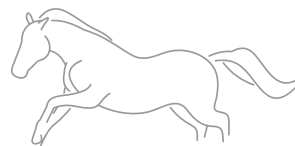
No treatment with
a medicinal product
possible

Non-food-producing equids:

For a equid to be considered as a non-food-producing animal, it must be declared in the horse passport as not intended for slaughter for human consumption, in accordance with Regulation 504/2008 and Article 112 of Regulation (EU) 2019/6.



***Restrictions to the use of antimicrobials may apply**



Responsibilities, Record-Keeping, and Product Use for Food-Producing and Companion Animals

Record-Keeping Guidelines and responsibility of the veterinarian

Veterinary responsibility: The use of the cascade is always the veterinarian's direct responsibility.

Record keeping: The veterinarian has to keep records of the VMPs used in the framework of the cascade for minimum 3 years (see national legislation)

- Date of examination
- Details of the owner
- Species
- Number of animals treated
- Diagnosis
- Medicinal product prescribed

and for food-producing animals:

- Doses administered
- Duration of treatment
- Recommended withdrawal period

How to Calculate the Withdrawal Period for Food-Producing Animals?

Withdrawal periods, as specified in Regulation (EU) 2019/6, Article 115, must be adhered to.

When determining the withdrawal period, follow these steps:

1. Check Regulation (EU) No 37/2010:

Verify whether the active substance is allowed for use in **food-producing** animals (see Table 1). Ensure the substance is permitted for the specific species and target tissues.

2. If the substance is listed in regulation (EU) N° 37/2010 but not for such species or such target tissues, refer to Regulation (EU) N° 2017/880

Follow the conditions outlined for extrapolation of withdrawal periods.

3. If no withdrawal period is established under the above regulations, apply the following minimum withdrawal periods:

For meat and offal:

- The longest withdrawal period provided in its summary of the product characteristics multiplied by **1.5**, or
- **28 days** for meat and offal if the medicinal product is not authorised for food-producing animals, or
- **1 day** if the medicinal product has a zero withdrawal period and is used in a different taxonomic family.

For milk:

- The longest withdrawal period provided in the summary of the product characteristics multiplied by factor **1.5**, or
- **7 days** if not authorised for animals producing milk for human consumption, or
- **1 day** if the medicinal product has a zero withdrawal period.

For eggs:

- The longest withdrawal period provided in the summary of the product characteristics for any animal species multiplied by factor **1.5**, or
- **10 days** if not authorised for animals producing eggs for human consumption

For fish meat, the withdrawal period must be at least:

- Longest withdrawal period for any aquatic species multiplied by **1.5** and expressed as degree-days, or
- if the medicinal product is authorised for food-producing terrestrial animal species, the longest withdrawal period for any of the food-producing animal species indicated in the summary of product characteristics multiplied by **50** and expressed as degree-days, but not exceeding 500 degree-days, or
- **500 degree-days**, if not authorised for food-producing animal species, or
- **25 degree-days**, if the highest withdrawal period for any species is zero.

Use of Third-Country Medicinal Products

Veterinarians may use non-immunological products authorised in a third country for the same species and indication only when all previous options have been exhausted.

A competent authority may permit the use of non-EU-authorized immunological veterinary products:

- During an outbreak of a listed disease (Article 5, Regulation 2016/429) or an emerging disease (Art 6, Regulation 2016/429).
- When the authorised product for an existing, non-listed disease in the Union is no longer available, to protect animal health, welfare, and public health.

Member State Availability or Shortage:

The Cascade can also be used if no product is temporarily available e.g. a shortage due to a supply issue in the veterinarian's Member State.

Use of antimicrobial medicinal products Art 107(6)

- Antimicrobials must **not be used routinely** or to compensate for poor hygiene, care, or farm management.
- Antimicrobials **cannot be used to promote growth or increase yield** in animals.
- **Prophylaxis restrictions:** Allowed only in exceptional cases for individual animals or small groups at high risk of severe infection.
- **Metaphylaxis conditions:** Permitted only when the risk of infection spread within a group is high, and no alternatives are available. Member States should provide guidance and promote criteria for its use.
- **Human-reserved antimicrobials:** Substances designated under Article 37(5) are not allowed to be used as per Articles 112, 113, and 114.

*** For the purposes of the Cascade, Iceland, Liechtenstein, and Norway are not considered third countries.**



List of substances which are essential for the treatment of equine species

Anaesthesia, analgesics and substances used in association with anaesthesia

• Sedation and premedication:

- Acepromazine
- Atipamezole
- Dexmedetomidine
- Flumazenil
- Naloxone
- Propofol
- Sarmazenil*
- Tiletamine*
- Zolazepam*

• Hypotension or respiratory stimulation during anaesthesia or systemic disorders:

- Allopurinol
- Dalteparin
- Dobutamine
- Dopamine
- Ephedrine
- Gelatin polysuccinate
- Glycopyrrolate
- Noradrenaline / norepinephrine
- Vasopressin

• Inhalation anaesthetics:

- Sevoflurane++

• Analgesia:

- Bromfenac
- Buprenorphine*
- Fentanyl
- Ketorolac
- Methocarbamol
- Morphine
- Pethidine*
- Triamcinolone acetonide

• Muscle relaxants and associated substances:

- Atracurium
- Cisatracurium
- Dantrolene sodium
- Edrophonium
- Guaifenesin

• Local anaesthetics

- Oxybuprocaine
- Prilocaine

• Substances for nervous system disorders

- Diazepam
- Midazolam++

Anti-inflammatory substances

• Corticosteroids

- Triamcinolone acetonide
- Flumethasone*

• Anti-endotoxins

- Pentoxifylline*
- Polymyxin B

Antimicrobials

• Bacterial keratitis

- Polymyxin B

• Gram-positive bacteria eye infection

- Fusidic acid
- Moxifloxacin
- Ofloxacin

• *Rhodococcus equi* infections:

- Azithromycin
- Clarithromycin
- Rifampicin*

• Septic arthritis

- Amikacin

Antifungals

- Amphotericin B
- Ketoconazole++
- Miconazole
- Nystatin
- Voriconazole

Antivirals

- Aciclovir
- Ganciclovir
- Valaciclovir

Antiprotozoal agents

- Isometamidium*
- Ponazuril*
- Pyrimethamine*

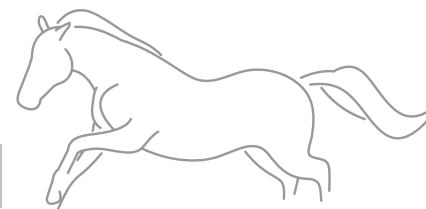
Tumours

- Imiquimod

Commission Regulation (EU) No 2025/901

*Substances listed in Commission Regulation (EU) No 122/2013, but not in the new Regulation (No 2025/901) not in the Implementing Regulation (EU) 2026/1810. Please note that these might be removed as of May 2027

++Substances listed in Commission Implementing Regulation (EU) 2026/1810



EQUIDAE

List of substances which are essential for the treatment of equine species

Ophthalmic medicines

- **Autoimmune diseases**
 - Cyclosporin A
- **Ocular ulcers**
 - Acyclovir
 - Idoxuridine*
- **Glaucoma**
 - Acetazolamide
 - Cyclosporin A
 - Fluoresceine
 - Ketorolac
 - Latanoprost*
 - Ofloxacin
 - Phenylephrine
 - Rose Bengal
 - Timolol maleate
 - Tropicamide*
- **Uveitis**
 - Tropicamide
 - Triamcinolone acetonide
- **Mydriatic agent**
 - Cyclopentolate
- **Treatment of the mucous membranes of the eye as a decongestant**
 - Tetryzoline
 - Synephrine

Rhabdomyolysis

-Dantrolene sodium

Miscellaneous

- Barium sulphate
 - Carbamazepine*
 - Cetirizine
 - Cyproheptadine*
 - Domperidone
 - Gabapentin*
 - Hydroxyethyl-starch*
 - Iohexol
 - Iopamidol*
 - Thyrotropin releasing hormone
 - Sulpiride

Hyperlipaemia

- Insulin

Diagnostic imaging/ diagnostic procedures

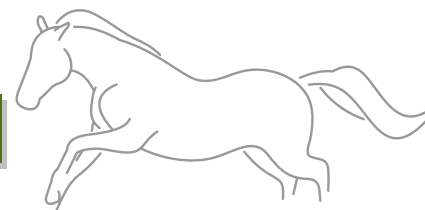
- Barium sulfate
 - Fluorescein
 - Iohexol
 - Phenylephrine
 - Rose Bengal
 - Radiopharma-ceutical Tc99m*
 -Thyrotropin releasing hormone

Convulsions

- Primidone*

Cardiovascular medicines

- Amiodarone
 - Allopurinol
 - Propafenone
 - Procainamide*
 - Propranolol*
 - Quinapril
 - Quinidine sulfate and quinidine gluconate
 - Sotalol
 - Verapamil
 - Vasopressin



Gastrointestinal agents

- Bethanechol*
 - Codeine*
 - Loperamide*
 - Metoclopramide
 - Misoprostol
 - Phenoxy-benzamine*
 - Phenylephrine
 - Propantheline bromide*
 - Ranitidine
 - Sucralfate

Respiratory medicines

- Ambroxol
 - Budesonide*
 - Fluticasone
 - Ipratropium bromide
 - Oxymetazoline
 - Phenylephrine

Commission Regulation (EU) No 2025/901

*Substances listed in Commission Regulation (EU) No 122/2013, but not in the new Regulation (No 2025/901) not in the Implementing Regulation (EU) 2026/1810. Please note that these might be removed as of May 2027

++Substances listed in Commission Implementing Regulation (EU) 2026/1810



Antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans

Antibiotics

- Carboxypenicillins
- Ureidopenicillins
- Ceftobiprole
- Ceftaroline
- Combinations of cephalosporins with beta-lactamase inhibitors
- Siderophore cephalosporins
- Carbapenems
- Penems
- Monobactams
- Phosphonic acid derivatives
- Glycopeptides
- Lipopeptides
- Oxazolidinones
- Fidaxomicin
- Plazomicin
- Glycylcyclines
- Eravacycline
- Omadacycline

Antiprotozoals

- Nitazoxanide

Antivirals

- Amantadine
- Baloxavir marboxil
- Celgosivir
- Favipiravir
- Galidesivir
- Lactimidomycin
- Laninamivir
- Methisazone/metisazone
- Molnupiravir
- Nitazoxanide
- Oseltamivir
- Peramivir
- Ribavirin
- Rimantadine
- Tizoxanide
- Triazavirin
- Umifenovir
- Zanamivir



Commission Implementing Regulation (EU) 2022/1255

List of antimicrobials which shall only be used under restrictions in cascade

Conditions on the use of antimicrobials	Target pathogen identification and AST	Restricted around certain indications	Restricted to use for certain indications only	Restricted from use in certain species	Use in individual animals only	Restriction on route of administration	HMPs only for use in individual animals
Aminopenicillin- BLI combinations	✓						
3rd & 4th generation cephalosporins	✓	<i>Salmonella</i>			✓		
Polymyxins	✓	<i>Salmonella</i>				✓	✓
Amphenicols	✓						
(Fluoro)quinolones	✓	<i>Salmonella</i>				✓	✓
Rifamycins (excl. EU-VMPs)	✓	Prophylaxis <i>R. equi</i>	<i>Mycobacteria</i> MDR <i>Staphylococcus</i>		✓		
TB drugs	✓				✓		
Riminofenazines	✓				✓		
Pseudemoniac acids	✓	Not for decolonisation	MRSA/P		✓	Topical only	
Remdesivir			FIP only				
Echinocandins	✓	Last resort			✓		
Amphotericin B		Last resort					