



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Veterinary medicines highlights 2018



## Authorisation of new medicines

Overview of the key figures on the European Medicines Agency's (EMA) recommendations for the authorisation of new veterinary medicines in 2018:

**10** Positive opinions

**4** New active substances

**3** Negative opinions

**2** Withdrawn applications

## New veterinary medicines

### Dogs



**Clevor**  
Cortacare  
**Isemid**

### Cattle



**Ubac**  
Syvazul BTV

### Cats



Bravecto Plus

### Chicken



Evant

### Honey bees



Dany's BienenWohl

### Horses



**Arti-Cell Forte**

### New born calves



Kriptazen

### Sheep



Syvazul BTV

Medicines that contain a new active substance are highlighted in green

## Innovations advancing animal health



### Dogs

**Isemid**

For the treatment of clinical signs related to congestive heart failure in dogs, including pulmonary oedema.



### Horses

**Arti-Cell Forte**

First stem cell-based veterinary medicine intended for the reduction of mild to moderate recurrent lameness associated with non-septic joint inflammation in horses.

## Medicines for minor use minor species (MUMS)\*



### Bees

**Dany's BienenWohl**

A powder and solution intended for the treatment of honey bees in hives infested by a parasite called varroa mite (*Varroa destructor*).



### Dogs

**Clevor**

A veterinary medicine used to induce vomiting in dogs and applied as an eye drop.



### Horses

**Arti-Cell Forte**

First stem cell-based veterinary medicine intended for the reduction of mild to moderate recurrent lameness associated with non-septic joint inflammation in horses.

\*Minor use veterinary medicines are intended for use in major species such as cattle, sheep, pigs, chicken, Atlantic salmon, cats and dogs, for the treatment of diseases that occur infrequently or occur in limited geographical areas. Minor species are all animals that are not one of the major species.

## Vaccines



### Cattle

#### Ubac ●

A vaccine intended to reduce clinical mastitis - udder infections with visible signs in milk or the udder, which can reduce milk production - caused by bacteria called *Streptococcus uberis*.



### Cattle and sheep

#### Syvazul BTV

A vaccine intended for active immunisation of sheep or cattle to prevent viraemia and reduce clinical signs and lesions caused by certain bluetongue virus serotypes.



### Chicken

#### Evant ●

A vaccine intended for active immunisation of chicks from 1 day of age against coccidiosis, a disease of the gut caused by parasites, which results in reduced growth, severe diarrhoea, reduced egg production and a high death rate.

● new medicines that might help reduce the need for antimicrobials in animals

## New uses for existing medicines

The use of 11 known substances was expanded in 2018:



### Credelio

To be also used in cats.



### Panacur AquaSol

To be also used for the treatment of *Capillaria spp.* in chickens.

### Onsior

To be also used for the treatment of pain and inflammation associated with chronic musculo-skeletal disorders in cats.

### Vectormune ND

To be also used in layer chickens.

### Semintra

To be also used for the treatment of systemic hypertension in cats.



### NexGard

#### Nexgard Spectra

To be also used for the treatment of demodicosis and sarcoptic mange.



### Advocate

To be also used for the treatment of, and protection against, further parasite species in cats and dogs.

### Pexion

To be also used for the reduction of anxiety and fear associated with noise phobia in dogs.



### Zulvac BTV

(formerly *Zulvac BTV Ovis*) to be also used in cattle.



### Metacam

To be also used in guinea pigs.



## Keeping medicines safe

Once a medicine has been put on the market, EMA and EU Member States continue to look at its quality and benefit/risk balance.

Important new safety advice issued in 2018 included:

- Veterinary medicines containing **enrofloxacin** for chickens and/or turkeys should no longer be used for treatment of infections caused by *E. coli*.
- If **diethanolamine** is to be further used in veterinary medicinal products for food producing species, an MRL evaluation would be required as a safety review could not rule out a risk for consumers.
- Histamine levels in **gentamicin**-containing veterinary medicines for horses need to be carefully controlled, with inclusion, where relevant, of a histamine limit in the active substance in order to minimise the possibility of adverse events.
- Include systemic and hypersensitivity reactions in the information on potential side effects of **Versican Plus L4**, **Versican Plus PiL4** and **Versican PiL4R** vaccines for dogs.
- Add special precautions and warnings in the product information for **Bravecto**, to ensure the safety of the person handling and administering the treatment.
- Include information on potential side effects such as anxiety or behavioural disorders for the treatment for epilepsy in dogs in the product information for **Pexion**.
- Issued new warnings and advice for **Osurnia**, regarding accidental eye exposure in the treated animal or accidental ingestion and skin contact in people handling the treatment.
- Add further advice in the product information for **Suvaxyn Circo+MH RTU** in case of accidental self-injection.
- Add further information in the package leaflet on potential side effects following administration of **Eryseng** and **Eryseng Parvo**, such as anaphylactic-type reactions.
- Amend the product information on potential side effects following administration of **Cytopoint** regarding gastrointestinal reactions.
- Add instructions to the product information for **Nobilis IB4-91** to ensure the safety of the person handling and administering the treatment.
- Add further information in the package leaflet on potential side effects following administration of **Rhiniseng**, such as anaphylactic-type reactions.



- Include further advice in the product information of **Easotic** on possible hearing deterioration following administration.
- Add further information in the package leaflet on potential side effects following administration of **MiPet Easecto** and **Simparica**, such as systemic reactions.
- Add further information in the package leaflet on potential side effects after administration of **Zycortal**, such as pancreas disorders.
- Amend the product information on potential side effects of **Credelio** in relation to gastrointestinal reactions.
- Add further information in the package leaflet on potential side effects of **Apoquel**, such as observations in changes to clinical pathology.



**If a medicine is supposed to be used in a food-producing animal, it needs to be safe for people to eat the food that comes from this animal. The maximum residue limits (MRLs) recommended by EMA reflect how much residue of the veterinary medicine in food derived from a treated animal is safe for consumption. The MRL is established before the medicine for food-producing animals is authorised in the EU.**

MRLs were established for the following active substances:

- **Ovotransferrin** - in chicken tissues and eggs, and tissues of other poultry species.

MRLs were extended to further species for the following active substances:

- **Paromomycin** - also for chicken eggs and eggs of other poultry species.
- **Isoflurane** - also for porcine species.

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EMA/878825/2018

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