Medicines Update: March 2023

This medicines update is provided by the Veterinary Medicines Directorate (VMD) and lists new active substance, new marketing authorisations and changes to authorisations most relevant to vets.

New marketing authorisations

Table 1 shows the new marketing authorisations for March 2023

TABLE 1: New marketing authorisations in March 2023

New Marketing Authorisations			
Product name and target species	**Active substance**	**Authorisation Holder, territory, and distribution category**	**Therapeutic group**
Non-Food Animals			
Bovilis Nasalgen-C Nasal Spray, Lyophilisate and Solvent for Suspension for Cattle	Bovine coronavirus	Intervet International BV NI POM-V	Live Viral Vaccine
Selaspot 15 mg Spot-on Solution for Cats and Dogs = 2.5 kg	Selamectin	Oy Medfiles Ltd UK POM-V	Endectocide
Selaspot 30 mg Spot-on Solution for Dogs 2.6 –60.0 kg	Selamectin	Oy Medfiles Ltd UK POM-V	Endectocide
Selaspot 45 mg Spot-on Solution for Cats 2.6 – – 10.0 kg	Selamectin	Oy Medfiles Ltd UK POM-V	Endectocide
Food Animals			
Moxisolv LA 100 mg/ml Solution for Injection for Cattle	Moxidectin	Bimeda Animal Health Limited GB & NI POM-VPS	Endectocide
EquiShield EHV, Emulsion for Injection for Horses	Equine herpesvirus 1	Dechra Regulatory BV GB POM-V	Inactivated Viral Vaccine
Brucellin Aquilon Solution for Injection for Pigs	Brucella abortus	Aquilón CyL S.L. NI POM-V	Diagnostic Preparation

See the VMD's Product Information Database (www.gov.uk/check-animal-medicine-licensed) for more information on each of these products. This includes separate links for the authorisation territories of Great Britain and Northern Ireland.

Please note, there may be a delay between the issuing of a marketing authorisation and the product being placed on the market.

Changes to authorisations most relevant to vets

The changes to authorisations most relevant to vets can be found below. Each product listed, along with the authorisation holder, distribution category and details of which Summary of Product Characteristics sections have been revised/changed.

All entries can be found on the VMD's Product Information Database at www.gov.uk/check-animal-medicine-licensed.

Changes to the SPC, labels and leaflets may change how the medicines should be used. There may be a delay between these changes being authorised to implementation on product literature. Unless you have been advised otherwise, the labelling instructions on the pack which is dispensed should be followed.

Food producing animals

Supaverm Oral Suspension

Elanco Europe Ltd. UK POM-VPS

Section 4.5i: As overdosage may result in signs of toxicity such as incoordination and blindness, care should be taken to ensure animals are not overdosed by volume. If the product is spilled, care should be taken to ensure animals do not ingest it.

Section 4.5ii: This product may be irritating to skin and eyes and users should be careful not to accidentally splash it on themselves or others. Wear impermeable rubber gloves when applying the product. Remove any contaminated clothing immediately. In case of accidental spillage onto skin or into eyes, rinse the affected area with large amounts of clean water. If irritation persists, seek medical advice immediately and show the package leaflet or label to the physician.

Section 4.5iii: This product is toxic to aquatic organisms and dung insects. Long-term effects on dung insects caused by continuous or repeated use cannot be excluded. Repeat treatments on a pasture within a season should only be given on the advice of the prescriber. To reduce the risk for dung fauna, if the worming protocol allows, treated and untreated animals should be grazed on the same field. The risk to aquatic ecosystems will be reduced by keeping treated animals away from water bodies for 48 hours after treatment.

Flovuxin 300/16.5 mg/ml Solution for Injection for Cattle

KRKA, d.d., Novo mesto NI & GB POM-V

Section 4.5i: Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

Section 4.6: Anaphylactic-type reaction are a very rare adverse event (<1 animal/10,000 animals treated, including isolated reports)

Deltamole 7.5 mg/ml Pour-on Suspension for Cattle

MSD Animal Health UK Limited UK POM-VPS

Section 4.3: Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Do not use on animals with major skin lesions.

Section 4.4: Cases of resistance to deltamethrin have been reported in stinging and nuisance flies in cattle. The product will reduce the number of flies resting directly on the animal, but it is not expected to eliminate all flies on a farm. Therefore, the use of this product should be based on local (regional and farm) epidemiological information about susceptibility of parasites and used in association with other pest management methods.
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- too frequent and repeated use of ectoparasiticides from the same class over an extended period of time;
- underdosing, which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of the dosing device.

If clinical signs do not resolve following treatment, the diagnosis should be revised.

Section 4.5i: Do not apply on or near the animal's eyes and mucous membranes.
Care should be taken to prevent the animal licking the product. Avoid use of the product during extremely hot weather and ensure animals have adequate access to water. The product should only be administered onto undamaged skin as toxicity is possible due to absorption from major skin lesions. However, signs of local irritation may occur after treatment as skin may already be affected by infestation.

Section 4.6: Application site reactions including erythema and pruritus, hyperactivity, anxiety and hypersensitivity have been reported in very rare cases in post-marketing experience.

Switch 4% w/v Pour-on Solution
VetPlus Ltd UK AVM-GSL Donkeys, Horses

Section 4.5ii: The product may cause neurotoxic effects and skin and eye irritation. Wash splashes from the skin and eyes immediately. If eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

Hexasol LA Solution for Injection for Cattle
Norbrook Laboratories Limited UK POM-V

Section 4.5: Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

Emdofluxin 50 mg/ml, Solution for Injection for Cattle, Pigs and Horses
Emdoka GB & NI POM-V

Section 4.5: Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

Bovimox 5 mg/ml Pour-on Solution for Cattle
Moxidectin EU Pharmaceuticals 5 mg/ml Pour-on Solution for Cattle
Ridamec 5 mg/ml Pour-on Solution for Cattle
Unomox 5 mg/ml Pour-on Solution for Cattle

EU Pharmaceuticals Ltd UK POM-VPS
and
Zermex 0.5% w/v Pour-on Solution for Cattle
Zoetis UK Limited UK POM-VPS

Section 4.3: Not to be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

Removed: All animals in a group should be treated.

Section 4.6: Neurological signs (including ataxia, trembling and lethargy) have been reported in very rare cases.

Suvaxyn PRRS MLV lyophilisate and solvent for suspension for injection for pigs
Zoetis Belgium NI POM-V

Section 4.2 and 5: Updated to include cross protection claim against the virulent heterologous PRRSV – 1 field strains (AUT15-33, BOR57 and Lena).

Draxxin Plus 100 mg/ml + 120 mg/ml Solution for Injection for Cattle

Zoetis UK Ltd GB POM-V

Section 4.6: Hypersensitivity reactions (e.g., anaphylaxis, dyspnoea, collapse) have been added as very rare adverse events (<1 animal/10,000 animals treated, including isolated reports). In case of such an allergic or anaphylactic reaction, appropriate symptomatic treatment should be administered immediately.

For more information, contact the VMD at postmaster@vmd.gov.uk