

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

12kg BAG

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flubenvet 5 % w/w Premix for Medicated Feeding Stuff

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram of white premix contains: 50 mg flubendazole

3. PHARMACEUTICAL FORM

Premix for Medicated Feeding Stuff

4. PACKAGE SIZE

12 kg

5. TARGET SPECIES

Pheasants, partridges, chickens, geese and turkeys
<pictograms of goose and chicken heads>

6. INDICATION(S)

Oral broad spectrum wormer for gamebirds and poultry
Effective against mature and immature stages and eggs of the following nematodes
of the gastrointestinal and respiratory tract:

Ascaridia galli (large roundworm)

Heterakis gallinarum (caecal worm)

Capillaria spp. (hair worm)

Amidostomum anseris (gizzard worm)

Trichostrongylus tenuis

Syngamus trachea (gapeworm).

Flubendazole has no adverse effect on egg-laying or hatchability.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For incorporation into dry feed at a registered mill.

A manufacturer who is approved to incorporate directly at any concentration,
veterinary medicinal products or premixtures containing such products, must be
responsible for mixing when incorporation is less than 2 kg per tonne for final feed.

Dosage

Pheasants and Partridges:

1.2 kg Flubenvet 5 % w/w Premix per tonne of feed (equivalent to 60 ppm
flubendazole).

Treat for 7 consecutive days.

Chickens and Geese:

600 g Flubenvet 5 % w/w Premix per tonne of feed (equivalent to 30 ppm flubendazole).

Treat for 7 consecutive days.

Turkeys:

400 g Flubenvet 5 % w/w Premix per tonne of feed (equivalent to 20 ppm flubendazole).

Treat for 7 consecutive days.

Incorporation

Add the required amount of Flubenvet 5 % w/w Premix to at least 5 kg of one of the feed ingredients and mix well.

Thoroughly mix this premix with the remaining ingredients, making in all one tonne of medicated feed, which can then be fed as pellets, mini-pellets, starter pellets or crumbs.

Treatment frequency

On infected premises, treatment at 3 weekly intervals may be necessary to control infestations.

8. WITHDRAWAL PERIOD(S)

Birds must not be slaughtered for human consumption during treatment.

Chickens, turkeys, geese, partridges and pheasants may be slaughtered for human consumption only after 7 days from the last treatment.

For chickens producing eggs for human consumption, the withholding period for eggs is zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Precautions:

Flubenvet 5 % w/w Premix may only be incorporated by approved manufacturers at the above incorporation rates.

Flubenvet 5 % w/w Premix can be incorporated into pelleted feed preconditioned with steam for up to 5 minutes at a temperature of 77 °C and can withstand pelleting temperatures up to 116 °C.

The product will remain stable in finished feed for up to eight weeks.

Operator Warnings:

Accidental ingestion by humans should be avoided. May cause sensitisation by skin contact. May cause skin and eye irritation. Avoid direct skin contact. Wear overalls, safety glasses and impervious gloves when mixing and handling the product. Wash affected parts if skin contact occurs. If accidental eye contact occurs, immediately rinse thoroughly with water.

If the operation involves potential exposure to dust, wear either a disposable filter and half mask respirator conforming to European Standard EN149, or a non-disposable respirator to European Standard EN140, fitted with a filter to EN 143.

10. EXPIRY DATE

Use by end: Refer to information on the bag.
The expiry date refers to the last day of that month.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Store in tightly closed original containers.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Rinse containers thoroughly with water.
Dispose of rinsings in slurry or dirty water.
Dispose of rinsed containers in the farm refuse.
Used containers should not be recycled.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY.
UK authorised veterinary medicinal product.

POM-VPS

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4184

17. MANUFACTURER’S BATCH NUMBER

Batch No: Refer to information on the bag.

OTHER INFORMATION

Manufacturers responsible for batch release:

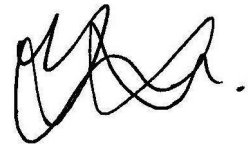
Elanco France S.A.S.
26 Rue de la Chapelle
68330 Huningue
France

Or

Laboratoria Smeets NV
Neerlandweg 24
B-2610 Wilrijk
Belgium

Or

Rumenco Limited, Trading as Nettex
Eastern Avenue, Lichfield, Staffordshire,
WS13 7SE,
United Kingdom

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 01 September 2022