

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

25 kg PRINTED BAG

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flubenol 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

25 kg

5. TARGET SPECIES

Pigs

<pictogram of pig head>

6. INDICATION(S)

Oral broad spectrum wormer for pigs

Effective against mature and immature stages and eggs of the following gastrointestinal and respiratory tract nematodes of pigs: *Ascaris suum* (large roundworm), *Hyoststrongylus rubidus* (red stomach worm), *Oesophagostomum dentatum* (nodular worm), *Metastrongylus apri* (lungworm), *Trichuris suis* (whipworm), *Strongyloides ransomi* (threadworm) (adult).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage

The standard recommended total dosage is 5 mg flubendazole per kg bodyweight. The amount of product to be incorporated should be calculated according to the average bodyweight of the pigs to be treated. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or over-dosing.

Incorporation and dosing instructions

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. As a guide, the following incorporation rates are suggested:

i) Standard dosing regime: Incorporation: add 600 g of Flubenol 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 mash or pellets. This gives 30 mg flubendazole per kg of finished feed.

Breeding stock should be treated for 10 consecutive days. Weaners and fattening pigs should be treated for 5 consecutive days, or in the event of heavy *Trichuris* infestation, for 10 consecutive days.

ii) Variable dosing regime: To facilitate feeding for different lengths of time to suit the intervals between feed deliveries, the standard dosage can be divided and administered over differing periods of time, as shown below.

Incorporation: add the required amount of Flubenol 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 mash or pellets.

a) Breeding stock

| Amount of Flubenol 5 % w/w to add to each 5 kg premix for making up each tonne of final feed | Flubendazole inclusion rate in final feed (mg/kg) | Duration of treatment (days) | Total dose of flubendazole (mg/kg bodyweight) | Uses |
|--|---|------------------------------|---|--|
| 400 g | 20 | 14 | 5 | <i>Ascaris suum</i> , <i>Oesophagostomum dentatum</i> and <i>Hyostrongylus rubidus</i> |
| 300 g | 15 | 21 | 5 | |
| 200 g | 10 | 28 | 5 | |

b) Weaners and fattening pigs

| Amount of Flubenol 5 % w/w to add to each 5 kg premix for making up each tonne of final feed | Flubendazole inclusion rate in final feed (mg/kg) | Duration of treatment (days) | Total dose of flubendazole (mg/kg bodyweight) | Uses |
|--|---|------------------------------|---|--|
| 200 g | 10 | 14 | 5 | <i>Ascaris suum</i> , <i>Oesophagostomum dentatum</i> and <i>Hyostrongylus rubidus</i> |
| 150 g | 7.5 | 21 | 5 | |

In the event of a heavy *Trichuris* infestation, use 600 g/tonne (30 mg/kg final feed) for 10 days.

Treatment frequency

Pigs should be treated twice a year unless recommended otherwise by a veterinary surgeon. Pigs brought onto the premises should be treated on arrival and before mixing with other animals. Consult a veterinary surgeon for initial identification of problem species. Treat relevant infestations at the intervals shown below:

Nodular worm: every 2 months
Large roundworm: every 2 months
Red stomach worm: every month
Whipworm: every 6 weeks
Lungworm: 3-4 weeks

8. WITHDRAWAL PERIOD(S)

Animals must not be slaughtered for human consumption during treatment. Pigs may be slaughtered for human consumption only after 7 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

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

Flubenol 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

POM-VPS

To be supplied only on veterinary prescription.
UK authorised veterinary medicinal product.

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
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4179

17. MANUFACTURER’S BATCH NUMBER

Batch: Refer to information on the bag.

FURTHER INFORMATION

Manufacturer responsible for batch release;

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

Or

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

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A handwritten signature in black ink, consisting of a stylized initial 'A' followed by the name 'Hunter.' with a period.