PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet
25 kg printed bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flubenol 5 % w/w Premix for Medicated Feeding Stuff

2. COMPOSITION

Each gram of white premix contains: 50 mg flubendazole

3. PACKAGE SIZE

25 kg

4. TARGET SPECIES

Pigs

5. INDICATIONS FOR USE

Indications for use

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), *Hyostrongylus rubidus* (red stomach worm), *Oesophagostomum dentatum* (nodular worm), *Metastrongylus apri* (lungworm), *Trichuris suis* (whipworm), *Strongyloides ransomi* (threadworm) (adult).

6. CONTRAINDICATIONS

Contraindications

7. SPECIAL WARNINGS

Special warnings

The veterinary medicinal product may only be incorporated by approved manufacturers at the above incorporation rates.

The veterinary medicinal product 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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 veterinary medicinal 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.

Overdose:

Flubendazole is an analog of mebendazole for which the side effects of overdose include transient gastrointestinal abnormalities.

8. ADVERSE EVENTS

Adverse events

Pigs:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details on this label, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

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 the veterinary medicinal product 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 the veterinary medicinal product 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 the veterinary medicinal product 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	*Ascaris suum, Oesophagostomum dentatum* and *Hyostrongylus rubidus*
300 g	15	21	5	
200 g	10	28	5	

b) Weaners and fattening pigs

Amount of the veterinary medicinal product 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	*Ascaris suum, Oesophagostomum dentatum* and *Hyostrongylus rubidus*
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

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: 7 days.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 00879/5064

Pack sizes

25 kg bag

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

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

Tel: +44 3308221732
PV.GBR@elancoah.com

Manufacturer responsible for batch release:

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

Or

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

18. OTHER INFORMATION

Other information

POM-VPS

Veterinary medicinal product subject to prescription

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

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

21. BATCH NUMBER

Lot {number}

Gavin Hall
Approved: 12 December 2025