

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
600g TUB

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flubenol 50 mg/g Oral Powder

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains: 50 mg flubendazole

3. PACKAGE SIZE

600g

4. TARGET SPECIES

Pigs.

5. INDICATIONS

Effective against mature and immature stages of the following gastro-intestinal tract nematodes of pigs.

Ascaris suum, (large roundworm), *Hyostrongylus rubidus*, (red stomach worm), *Oesophagostomum dentatum* (nodular worm), *Trichuris suis* (whipworm) and *Strongyloides ransomi* (threadworm) (adult).

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 7 days

8. EXPIRY DATE

Exp. {mm/yyyy}

Prepare immediately before use; discard any unused feed at the end of the day.

9. SPECIAL STORAGE PRECAUTIONS

Keep the container tightly closed.
Do not store above 25 °C

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd

14. MARKETING AUTHORISATION NUMBER

Vm 00879/4183

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Flubenol 50 mg/g Oral Powder

2. Composition

Each gram contains: 50 mg flubendazole

White powder.

3. Target species

Pigs

4. Indications for use

Effective against mature and immature stages of the following gastro-intestinal tract nematodes of pigs.

Ascaris suum, (large roundworm), *Hyostrongylus rubidus*, (red stomach worm), *Oesophagostomum dentatum* (nodular worm), *Trichuris suis* (whipworm) and *Strongyloides ransomi* (threadworm) (adult).

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:

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 anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

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. Personal protective equipment consisting of overalls, safety glasses and impervious gloves should be worn when 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 on a half mask respirator, conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 fitted with a filter to EN 143.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Overdose:

Flubendazole has a low acute oral toxicity and is well tolerated in the target species. In situations where accidental overdose is suspected of having occurred, there is no antidote and treatment should be symptomatic.

7. Adverse events

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 in this package leaflet, 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 at the end of this leaflet, 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

8. Dosage for each species, routes and method of administration

For oral use.

One 600 g tub treats 40 sows.

To ensure a correct dosage, body weight should be determined as accurately as possible. 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 overdosing.

Individual treatment (single administration):

i. Dosage:

One 13 g measuring spoon treats one 130 kg sow. Add 1 g of the veterinary medicinal product for each 10 kg bodyweight onto the finished feed for each individual animal. This is equivalent to 5 mg of flubendazole per one kg bodyweight.

ii. Treatment frequency:

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. Regular faecal examination is advocated to know which worms are present on the farm so that specific measures may be taken to prevent re-infection. Consult a veterinary surgeon for initial identification of problem species.

iii. Treatment of clinical worm infestations:

Treat relevant infestations at the following intervals:

Nodular worm (<i>Oesophagostomum dentatum</i>)	-	every 2 months
Large roundworm (<i>Ascaris suum</i>)	-	every 2 months
Red stomach worm (<i>Hyostrogylus rubidus</i>)	-	every month
Whipworm (<i>Trichuris suis</i>)	-	every 6 weeks.

9. Advice on correct administration

10. Withdrawal periods

Meat and offal: 7 days

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the container tightly closed.

Do not store above 25 °C.

Prepare immediately before use; discard any unused feed at the end of the day.

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.

12. 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 00879/4183

Pack sizes

600g tub, with 20 ml measuring spoon.

15. 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.

16. Contact details

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

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

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

17. Other information

POM-
VPS

Veterinary medicinal product subject to prescription

Gavin Hall

Approved: 16 September 2025