MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flubenol 5% w/w Oral Powder for Pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Each gram contains:

50 mg flubendazole as active.

4. PHARMACEUTICAL FORM

Oral powder

5. PACKAGE SIZE

600g

6. INDICATION(S)

Front and Base Label:

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

Inner:

Flubenol 5% w/w Oral Powder is 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).

7. CONTRAINDICATIONS

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

8. ADVERSE REACTIONS

9. TARGET SPECIES

Pigs

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral use. One 600 g tub treats 40 sows.
To ensure administration of a correct dose, 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 Flubenol 5% w/w Oral Powder 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 (*Oesophagostomum dentatum*)	-	every 2 months
Large roundworm (*Ascaris suum*)	-	every 2 months
Red stomach worm (*Hyostrongylus rubidus*)	-	every month
Whipworm (*Trichuris suis*)	-	every 6 weeks.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Meat and offal: 7 days

Pigs must not be slaughtered for human consumption during treatment.

13. SPECIAL STORAGE PRECAUTIONS

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

14. SPECIAL WARNING(S)

Special warnings for each target species

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. 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 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.

15. EXPIRY DATE

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

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

Any unused veterinary medicinal product or waste materials from such veterinary medicinal products should be disposed of in accordance with local requirements.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

April 2024

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

[Distribution category]

POM-VPS

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children

20. MARKETING AUTHORISATION NUMBER

Vm 00879/4183

21. MANUFACTURER'S BATCH NUMBER

Approved: 18 June 2024

Gavin Hall