1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flubendazole Elanco 50 mg/g oral powder for pigs (IE)
Flubenol 50 mg/g oral powder for pigs (FR, PL)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:

50 mg flubendazole

Excipients:

Qualitative composition of excipients and other constituents
Sodium laurilsulfate
Lactose monohydrate

White to slightly yellow powder.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

Treatment of helminthiasis due to mature and immature stages of the following nematodes of the gastro-intestinal tract:

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

Flubendazole is ovicidal.

3.3 Contraindications

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

3.4 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

May cause sensitisation by skin contact. May cause skin and eye irritation. Wash hands after use. Accidental ingestion by humans should be avoided. Personal protective equipment consisting of overalls, safety glasses and impervious gloves should be worn when handling and mixing 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 EN143.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used in pregnant and lactating animals.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

To ensure a correct dosage, body weight should be determined as accurately as possible. Prepare immediately before use; discard any unused feed at the end of the day.

Individual treatment (single administration):

Dosage:
5 mg of flubendazole per one kg of bodyweight as a single administration, equivalent to 1 g of powder for each 10 kg bodyweight into the finished feed. One measuring spoon treats one 130 kg sow.

Treatment frequency:
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.

Treatment of clinical worm infestations:
The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. As with other anthelmintics, veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of resistance developing.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 7 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC12

4.2 Pharmacodynamics

Flubendazole is a synthetic anthelmintic belonging to the benzimidazole carbamates. It acts by binding to tubulin, the dimeric subunit protein of the microtubules. It inhibits microtubular assembly in absorptive cells: i.e. of intestinal cells of nematodes or the tegumental cells of cestodes. This is shown by disappearance of cytoplasmic microtubules, accumulation of secretory granules in the cytoplasm due to a block in their transport, leading to an impaired coating of the cellular membrane and a decreased digestion and absorption of nutrients. Irreversible lytic degeneration of the cell, due to the accumulation of secretory substances (hydrolytic and proteolytic enzymes), results in the death of the parasite. These changes are relatively fast and are primarily seen in those organelles directly involved in the secretory and absorptive functions of the cells. In contrast the changes are not seen in host cells.

4.3 Pharmacokinetics

Flubendazole is very poorly soluble in aqueous systems, such as the gastrointestinal tract, which results in a low dissolution rate and a very low absorption. This is reflected by a high faecal excretion of unchanged parent drug. The very small fraction absorbed is extensively metabolised by first-pass metabolism in the liver, involving carbamate hydrolysis and ketone reduction. The biotransformation products are conjugated to glucuronides or sulphate conjugates and excreted in the bile and the urine.
The excretion in urine is relatively low and consists almost exclusively of metabolites with only small amounts of unchanged compound. In pigs, highest tissue levels are measured in liver and kidneys. The half-life of flubendazole in tissues is 1 to 2 days.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf-life after first opening the immediate packaging: 3 months.

5.3 Special precautions for storage

Keep the container tightly closed.

5.4 Nature and composition of immediate packaging

600 g polypropylene container closed with a low density polyethylene (LDPE) push cap.
The product is accompanied with a polypropylene spoon.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database *(https://medicines.health.europa.eu/veterinary)*.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

PP CONTAINER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flubendazole Elanco 50 mg/g oral powder (IE)
Flubenol 50 mg/g oral powder (FR, PL)

2. STATEMENT OF ACTIVE SUBSTANCES

50 mg/g flubendazole

3. PACKAGE SIZE

600 g

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period: Meat and offal: 7 days.

8. EXPIRY DATE

Shelf-life after first opening the immediate packaging: 3 months.
Once opened, use by ...

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Keep the container tightly closed.

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 logo

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Flubendazole Elanco 50 mg/g oral powder for pigs (IE)
Flubenol 50 mg/g oral powder for pigs (FR, PL)

2. Composition

Each g contains:
Active substance:
50 mg flubendazole

White to slightly yellow powder.

3. Target species

Pigs.

4. Indications for use

Treatment of helminthiasis due to mature and immature stages of the following nematodes of the gastro-intestinal tract:

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

Flubendazole is ovicidal.

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:
May cause sensitisation by skin contact. May cause skin and eye irritation.

Wash hands after use. Accidental ingestion by humans should be avoided. Personal protective equipment consisting of overalls, safety glasses and impervious gloves should be worn when handling and mixing 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.

Pregnancy and lactation:
Can be used in pregnant and lactating animals.

Interaction with other medicinal products and other forms of interaction:
None known.

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

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

None.

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: {national system details}.

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

Oral use.

Individual treatment (single administration):

Dosage:
5 mg of flubendazole per one kg of bodyweight as a single administration, equivalent to 1 g of powder for each 10 kg bodyweight into the finished feed. One measuring spoon treats one 130 kg sow.

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.

Treatment of clinical worm infestations:
The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. As with other anthelmintics, veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of resistance developing.

9. Advice on correct administration

Underdosing could result in ineffective use and may favour resistance development. To ensure a correct dosage, body weight should be determined as accurately as possible.
Prepare immediately before use; discard any unused feed at the end of the day.

10. Withdrawal periods

Meat and offal: 7 days.

11. Special storage precautions

Keep the container tightly closed.
Keep out of the sight and reach of children.
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.
Shelf-life after first opening the immediate packaging: 3 months.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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

600 g polypropylene container closed with a low density polyethylene (LDPE) push cap.
The product is accompanied with a polypropylene spoon.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven

Germany

Manufacturer responsible for batch release:
Elanco France S.A.S.
26 Rue de la Chapelle
68330 Huningue
France

17. Other information