Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Flubendazole Elanco 50 mg/g oral powder for pigs.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:
Flubendazole 50mg

Excipient(s):
Titanium dioxide (E171) 20mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral Powder.

White to slightly yellow powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the 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), *Strongyloidesransomi* (threadworm) (adult).

Flubendazole is ovicidal.

4.3 Contraindications

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

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

Wash hands after use. 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 EN143.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product may be used in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Meat and offal: 7 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Benzimidazoles and related substances; Flubendazole.
ATCvet code: QP52AC12

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Titanium dioxide (E171)
Sodium laurilsulfate
Lactose monohydrate

6.2 Major incompatibilities

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

6.3 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

6.4 Special precautions for storage

Keep the container tightly closed.

6.5 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.

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

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

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/037/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd February 2013
Date of last renewal: 22nd February 2018

10 DATE OF REVISION OF THE TEXT

July 2018