IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10545/024/001**
Case No: 7001900

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

Janssen Cilag Ltd.

Saunderton, **High Wycombe**, **Buckinghamshire HP14 4HJ**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Flubenol 50% Premix

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Flubenol 50 % Premix.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient
Flubendazole 500 mg/g (50 %w/w)

Other ingredients include lactose monohydrate.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Medicated premix.

4 CLINICAL PARTICULARS

4.1 Target Species

Pig.

4.2 Indications for use, specifying the target species

Flubendazole is a broad spectrum anthelmintic, effective against mature and immature stages of the following nematodes of the gastrointestinal and respiratory tract:

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

Flubendazole is ovicidal.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

None known.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

No adverse reactions known during pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

i) Incorporation

60g of Flubenol 50% Premix to at least 5kg 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 30mg flubendazole per kg of finished feed.

The product can be incorporated into pelleted feed, preconditioned with steam up to 5 minutes at a temperature of 77ºC and can withstand pelleting temperatures up to 116ºC.
When used as recommended this product should only be incorporated by approved manufacturers.

ii) Dosage

a) Breeding stock - feed for 10 consecutive days to control all worm species above.

b) Weaners and fattening pigs - feed for 5 consecutive days. In the event of a heavy Trichuris infestation, feed for 10 consecutive days.

iii) 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.

iv) Treatment of Clinical Worm Infestations

Treat relevant infestations at the following intervals:

Lungworm (*Metastrongylus apri*)	-	every 3-4 weeks
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

Consult a veterinary surgeon for initial identification of problem species.

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

Supportive therapy if required.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment.

Meat: 7 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Summary Presentation of the Active Ingredient

Flubendazole is a synthetic anthelmintic belonging to the benzimidazole carbamates which acts by inhibiting the microtubular assembly in absorptive cells of nematodes and cestodes.

5.1 Pharmacodynamic properties

Flubendazole acts by binding to tubulin, the dimeric sub-unit 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 properties

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

Sodium Lauryl Sulphate
Colloidal Anhydrous Silica
Lactose Monohydrate

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

The expiry date shall not be more than 60 months from the date of manufacture. The product will remain stable in the finished feed for 2 months.

6.4 Special precautions for storage

Store in a tightly closed original containers below 25°C.

6.5 Nature and composition of immediate packaging

Container:	Multi-layered paper bag with internal low density polyethylene (LDPE) layer.
Closure:	Not applicable.
Dosing device:	Not applicable.
Container size:	10 Kg

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Janssen-Cilag Ltd.
P.O. Box 79
Saunderton
High Wycombe
Buckinghamshire HP14 4HJ
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10545/24/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19th April 2002

10 DATE OF REVISION OF THE TEXT

21st November 2006