IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10545/026/001**
Case No: 7002058

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 Easy 220 mg chewable tablets

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 Easy 220 mg Chewable tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance

Flubendazole 220 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

Treatment of adult worm infestations in dogs with:

Roundworms
Toxocara canis
Toxascaris leonina
Hookworms
Uncinaria stenocephala
Ancylostoma caninum
Whipworm
Trichuris vulpis
Tapeworm
Taenia pisiformis

4.3 Contraindications

Do not use in animals known to be hypersensitive to the active substance.

4.4 Special warnings for each target species

Not known

4.5 Special precautions for use

Special precautions for use in animals

None known.

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

Wash hands after handling tablets and after administration to dogs.

4.6 Adverse reactions (frequency and seriousness)

Flubenol Easy is well tolerated
Occasional transient vomiting and mild diarrhoea have been observed

4.7 Use during pregnancy, lactation or lay

Flubenol Easy can be safely used during pregnancy and in lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Posology
1 tablet per 10 kg body weight = 22mg/kg bodyweight.

Dosing Scheme
Dogs infested with ascarids and/or hookworms only:
1 tablet per 10 kg bodyweight, once a day for 2 consecutive days.

Examples

Dog's weight	**1st day**	**2nd day**	**Total number of tablets**
2.5 – 5 kg	Half	Half	1
5.1 – 10 kg	One	One	2
10.1 – 15 kg	One and a Half	One and a Half	3
15.1 – 20 kg	Two	Two	4
20.1 – 25 kg	Two and a Half	Two and a Half	5

For each additional 5 kg bodyweight, give an additional half tablet each day.
For dogs less than 2.5kg bodyweight (eg puppies and toy breeds), a quarter of a tablet may be given each day.

Dosing Scheme
Dogs with *Trichuris vulpis* and *Taenia pisiformis* infestations:
1 tablet per 10 kg bodyweight, once a day for 3 consecutive days.

Examples

Dog's weight	**1st day**	**2nd day**	**3rd day**	**Total number of tablets**
2.5 – 5 kg	Half	Half	Half	1½
5.1 – 10 kg	One	One	One	3
10.1 – 15 kg	One and a Half	One and a Half	One and a Half	4½
15.1 – 20 kg	Two	Two	Two	6
20.1 – 25 kg	Two and a Half	Two and a Half	Two and a Half	7½

For each additional 5 kg bodyweight, give an additional half tablet each day.

For dogs less than 2.5kg bodyweight (eg puppies and toy breeds), a quarter of a tablet may be given each day.

Method of administration
In most cases, the tablet(s) can be administered as a treat to the dog, no further action being needed. Alternatively, the tablet(s) can be administered by putting them on the back of the tongue or they can be mixed in a small portion of feed.

Suggested treatment schedule
Young dogs: -at weaning and then every 2 to 3 months
Bitches: -prior to service
-10 days before and 10 days after whelping

Adult dogs: -3 to 4 times a year

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

No clinical side effects even at overdosage of up to three times the recommended dose are expected. Doses above this level may result in raised liver enzyme levels.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Summary presentation of the active ingredient
ATCVet code: QP52AC12
Flubenol contains the benzimidazole flubendazole, a synthetic broad-spectrum anthelmintic effective against ascarids, hookworms, whipworm and tapeworm found in dogs.

5.1 Pharmacodynamic properties

Flubendazole has a rapid and selective action on gastro-intestinal parasites: the interaction of flubendazole with the microtubular system of the absorptive cells of the worm leads to autolysis and complete cell necrosis. This results in death and expulsion of the worm.

5.2 Pharmacokinetic properties

Flubendazole is poorly soluble in aqueous systems such as the gastro-intestinal tract.
This results in a low dissolution rate and a low oral bioavailability, as reflected by a high faecal excretion of the parent drug.
Within 4 days of an experimental 10-mg/kg dose of radio-labelled flubendazole, dogs excreted more than 80% in the faeces and less than 10% in the urine. Parent flubendazole accounted for more than 90% of the faecal residue, but the residue in urine consisted almost exclusively of metabolites. The absorbed fraction was extensively transformed by a first-pass metabolism in the live due to hydrolysis of the carbamate and the reduction of the ketone. These metabolities were conjugated with glucuronic acid or sulphate and excreted in the urine. Due to the low absorption and the first-pass metabolism, the maximum concentrations of flubendazole in plasma following the 10-mg/kg dose were lower than 10 ng/ml and were reached at 24 to 48 hours after dosing. The plasma half-life of flubendazole and its metabolites was about 16 hours.

Oral administration of flubendazole in chewable tablets at the therapeutic dose of 22 mg/kg results in low plasma concentrations. At 2-8 hours after administration, maximum plasma concentrations of flubendazole not exceeding 30 ng/ml are reached. Considerable individual variation in plasma concentrations may occur and the feed regimen may influence $t_{max.}$ Both observations are without clinical significance, as the bioavailability invariably remains low.

There is no pronounced difference in systemic availability after a first or a second and third treatment day.
Administration at 3 to 5 fold multiples of the therapeutic dose results in a less than linear (<2) increase of the absorbed flubendazole.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dried brewer's yeast lysate
Cellulose, Microcrystalline
Sorbitol
Hypromellose
Silica, Colloidal Anhydrous
Magnesium stearate
Sodium Lauryl Sulphate
Beef flavour

6.2 Incompatibilities

None known.

6.3 Shelf-life

36 months.

6.4 Special precautions for storage

Keep in the original pack.
Store below 25°C

6.5 Nature and composition of immediate packaging

Cartons containing (3) (6) (9) tablets in PVC-PE-PVDC/Aluminium foil blister.

Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Janssen-Cilag Ltd
Saunderton
High Wycombe
Buckinghamshire
HP14 4HJ
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10545/26/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5th November 2004

10 DATE OF REVISION OF THE TEXT

9th November 2006