IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10545/027/001**
Case No: 7001100

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:

Furexel 1.87% Oral Paste

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.

The authorisation, unless previously revoked, shall continue in force from **21/02/2007**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

Furexel 1.87% Oral Paste

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	
Ivermectin	1.87 % w/w

Excipient	
Titanium dioxide (E 171)	2.0 % w/w

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Oral paste.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses.

4.2 Indications for use, specifying the target species

The product is indicated for the treatment of parasitic infestations in horses due to:

Large strongyles

Strongylus vulgaris (adults and arterial larval stages)
S. edentatus (adults and tissue stages)
S. equinus (adults)
Triodontophorus spp. (adults)

Small strongyles (adults and immatures) including benzimidazole-resistant strains

Cyathostomum spp.
Cylicocyclus spp.
Cylicostephanus spp.
Cylicodontophorus spp.
Gyalocephalus spp.

Lungworms (adults and immatures)
Dictyocaulus arnfieldi

Pinworms (adults and immatures)
Oxyuris equi

Ascarids (adults and immatures)
Parascaris equorum

Hairworms (adults)
Trichostrongylus axei

Large-mouth stomach worms (adults)
Habronema muscae

Neck threadworms (microfilariae)
Onchocerca spp.

Intestinal threadworms (adults)
Strongyloides westeri

Stomach bots
Oral and gastric stages of *Gastrophilus* spp.

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 precautions for use in animals

No special precautions are required.

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

Do not smoke or eat while handling the product.
Wash hands after use.
Do not allow cats or dogs to ingest spilled paste or access to used syringes.

4.6 Adverse reactions (frequency and seriousness)

Some horses carrying heavy infection of *Onchocerca microfilariae* have experienced oedema and pruritus following dosing, assumed to be the result of death of large numbers of microfilariae. These signs resolve within a few days but symptomatic treatment may be advisable.

4.7 Use during pregnancy, lactation or lay

The product can be administered to mares at any stage of pregnancy or lactation. The product will not affect the fertility of breeding mares and stallions and can be given to all ages of animals including young foals.

4.8 Interaction with other medicinal products and other forms of interaction

The product has been used in conjunction with other equine health care products and no interactions have been identified.

4.9 Amounts to be administered and administration route

The product is given orally at the recommended dose level of 0.2 mg ivermectin per kilogram of bodyweight. Each syringe delivers 120 mg ivermectin, sufficient to treat 600 kg of bodyweight.

Dosing instructions

Each weight marking on the syringe plunger will deliver sufficient paste to treat 100 kg bodyweight. Unlock the knurled ring by making ¼ turn and slide the knurled ring up the plunger shaft so that the side nearest the barrel is at the prescribed weight marking. Turn the knurled ring ¼ turn to lock in place. Remove the plastic cap from the tip of the nozzle. Make sure the horse's mouth contains no feed. Insert the syringe into the horse's mouth at the interdental space. Advance the plunger as far as it will go, depositing the medication on the base of the tongue.

Parasite control program

All horses should be included in a regular parasite control programme, with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at 6 to 8 weeks of age, and routine treatment repeated as appropriate.
The product is highly effective against gastro-intestinal, cutaneous and pulmonary nematodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis and colic caused by *Strongylus vulgaris*. With its broad spectrum, the product is well suited to be the major component in a rotational programme.

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

Mild transitory signs (slowed pupillary light response and depression) have been seen at a dose of 1.8 mg/kg (9 times the recommended dose level). Other signs seen at higher doses include mydriasis, ataxia, tremors, stupor, coma and death. The less severe signs have been transitory. No antidote has been identified; however, symptomatic therapy may be beneficial.

4.11 Withdrawal Period(s)

Meat: Animals intended for human consumption must not be slaughtered during treatment.
Animals intended for human consumption may only be slaughtered from 21 days after the last treatment.
Milk: Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The avermectin family of compounds, of which ivermectin is a member, kills certain parasitic nematodes and arthropods. The mode of action is unique to the avermectin class of antiparasitic agents and involves a chemical that serves as a signal from one nerve cell to another, or from a nerve cell to a muscle cell. This chemical, a neurotransmitter, is called a gamma-aminobutyric acid or GABA.

In roundworms ivermectin stimulates the release of GABA from nerve endings and enhances binding of GABA to special receptors at nerve junctions, thus interrupting nerve impulses - thereby paralysing and killing the parasite. The enhancement of the GABA effect in arthropods such as mites and lice resembles that in roundworms except that nerve impulses are interrupted between the nerve ending and the muscle cells. Again, this leads to paralysis and death in most species.

Ivermectin has no measurable effect against flukes or tapeworms, presumably because they do not have GABA as a nerve impulse transmitter. Recommended doses have a wide safety margin in livestock. The principal peripheral neurotransmitter in mammals, acetylcholine, in unaffected by ivermectin. Ivermectin does not readily penetrate the central nervous system of mammals where GABA functions as a neurotransmitter.

5.2 Pharmacokinetic properties

Maximum plasma concentration

The maximum plasma concentration (average of 32 ng/ml) is reached 6 hours after administration of a dose rate of 0.3 ivermectin per kg bodyweight. This peak falls off gradually to an average level of 2 ng/ml at 10 days.

Excretion: length of time and route

Ivermectin residues (expressed as hihydro B_{1a}) in the liver, muscle, kidney, fat and blood were determined with a liquid chromatographic method with fluorescence detection. No residue (except one 28 day fat sample) reached the limit of detection of > 2ppb 21, 28 and 42 days post dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropylcellulose
Hydrogenated Castor Oil
Titanium Dioxide E171
Propylene Glycol

6.2 Incompatibilities

No major incompatibility has been identified.

6.3 Shelf-life

The expiry date shall be not more than 36 months from the date of manufacture.

6.4 Special precautions for storage

Do not store above 25ºC
Protect from light

6.5 Nature and composition of immediate packaging

Disposable polypropylene syringes containing 6.42g paste in cartons, each containing one syringe.

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

Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive. Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations. Do not contaminate lakes or streams as free ivermectin may adversely affect fish and certain water-borne organisms.

7 MARKETING AUTHORISATION HOLDER

Janssen-Cilag Limited,
PO Box 79,
Saunderton,
High Wycombe,
Bucks, HP14 4HJ,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10545/27/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21st February 2007