IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10545/009/001**
Case No: 7004500

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Janssen Cilag Ltd.

50-100 Holmers Farm Way, **High Wycombe**, **Buckinghamshire HP12 4EG**, **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:

Telmin Granules 100mg/g

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 revoked, shall continue in force from **09/07/2008** until **30/09/2009**.

Signed on behalf of the Irish Medicines Board

_____

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

Telmin Granules 100mg/g

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:	**Quantity:**
Mebendazole	100 mg

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Granules
Slightly amber granules for addition to feed.

4 CLINICAL PARTICULARS

4.1 Target Species

Horse and donkey

4.2 Indications for use, specifying the target species

An oral broad spectrum anthelmintic for the treatment of helminthiasis in the horse and donkey. Telmin is effective against benzimidazole - susceptible strains of the following worms:

Large strongyles:	*Strongylus vulgaris*
	Strongylus edentatus
	Strongylus equinus
Small strongyles:	*Cyathostomes*
	Triodontophorus spp.
	Trichostrongylus axei
Ascarids:	*Parascaris equorum*
Pinworms:	*Oxyuris equi*
	Probstmayria vivipara
Lungworms:	*Dictyocaulus arnfieldi*.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.
Do not treat animals during the first 4 months of pregnancy with doses of 15 mg/kg or over.

4.4 Special warnings for each target species

Horses which are too thin or prone to colic must be examined by a veterinary surgeon prior to treatment.

4.5 Special precautions for use

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your veterinary surgeon.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

See section 4.3 – Contra-indications

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

The dose rate is 5-10 mg mebendazole per kg bodyweight orally. Repeat this dose every 6 weeks.

Animals 200-400 kg - 1 sachet
Animals 400-800 kg - 2 sachets

For the treatment of *Dictyocaulus arnfieldi* infections, give orally at the rate of 15-20 mg mebendazole per kg bodyweight daily for 5 consecutive days.
Administer the granules with the normal feed taking care to ensure even mixing. Concentrated feed can be moistened a little if necessary. Previous fasting is not necessary.
Assess bodyweight as accurately as possible before calculating the dosage.

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

Supportive therapy if required.

4.11 Withdrawal Period(s)

Animals for human consumption must not be slaughtered until 6 months after treatment with Telmin Granules.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mebendazole is an anthelmintic belonging to the benzimidazole group of compounds with efficacy against certain gastrointestinal roundworms and lungworms in horses and donkeys.

Mebendazole acts selectively against the gastrointestinal and lung parasites in the host. It is based on an interaction with the microtubular system of the absorptive cells of the worm, leading to an irreversible lytic necrosis of those cells and death of the worm.

5.2 Pharmacokinetic properties

The pharmacokinetic profile of mebendazole is similar in various animal species, including horses. Mebendazole has a poor oral bioavailability, due to a low solubility in aqueous systems, a slow dissolution rate in the gastrointestinal tract and first-pass metabolism in the gut wall and the liver. This causes a high faecal excretion of parent drug and low levels in plasma and tissues. Absorption is not linearly dependent of dose. Highest concentrations of mebendazole-related residues are found in the liver and kidneys and these consist mainly of metabolites. The biotransformation of mebendazole involves carbamate hydrolysis, ketone reduction and conjugation. The elimination from plasma and tissues is rapid, although there is some retention of residues in the liver.

The systemic bioavailability of mebendazole in horses is very low, irrespective of the oral dosage form. After a 6.5 mg/kg dose, the concentrations in plasma never exceed 10 ng/ml.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Maize Starch
Acacia

6.2 Incompatibilities

Not applicable

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale:
5 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Aluminium foil sachet containing 20 g granules.
Available as cartons containing 2 x 20 g sachets.

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.
50 - 100 Holmers Farm way
High Wycombe,
Buckinghamshire,
HP12 4EG,
UK.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10545/9/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2004

10 DATE OF REVISION OF THE TEXT

9th July 2008