Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Telmin 200 mg/g Oral Paste.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:	
Menbendazole	200.0 mg
Excipients:	
Methyl Parahydroxybenzoate	1.902 mg
Propyl Parahydroxybenzoate	0.212 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral paste
Beige.

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
	Triodontophorus spp.
Small strongyles:	*Cyathostomes*
	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

For use in donkeys at a higher dose rate, see Section 4.9

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

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.
Resistance to mebendazole (a benzimidazole) has been reported in cyathostomes in horses within the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.
To reduce this risk, dosing programmes should be discussed with your veterinary surgeon.

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.
Persons with known hypersensitivity to ingredients in the product should not handle the product.
Avoid contact with skin and eyes. Wash off any splashes immediately with clean running water. Seek medical attention if irritation persists.

4.6 Adverse reactions (frequency and seriousness)

None reported.

4.7 Use during pregnancy, lactation or lay

Animals should not be treated with a dose of 15 mg/kg or over during the first 4 months of pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Route of administration: Oral

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible.

Horses:
The dose rate is 5 – 10 mg mebendazole per kg bodyweight.
1 syringe will treat a horse of 400 - 800 kg.
This dose can be repeated every 6 weeks.

Donkeys:
For the treatment of *Dictyocaulus arnfieldi* give orally at the rate of 15-20 mg mebendazole per kg bodyweight daily for 5 consecutive days.
1 syringe will treat a donkey of 200 - 270 kg.

This is a single dose product. Part syringe doses must not be used due to the potential for inconsistency in the distribution of the active substance within the syringe.
An alternative product should be used to treat foals, horses weighing less than 400 kg and donkeys weighing less than 200 kg or more than 270 kg.

Administer by squeezing the paste from the syringe onto the back of the tongue.
Previous fasting is not required.

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.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Anthelmintics; Benzimidazoles and related substances; Mebendazole.

ATCvet Code: QP52AC09.

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

Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Sorbitan Stearate
Polysorbate 60
Liquid Paraffin
Methyl Cellulose
Water, Purified
Citric Acid *(for pH adjustment)*
Sodium Hydroxide *(for pH adjustment)*

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

6.4 Special precautions for storage

Do not store above 25^{o}C.
Discard any remaining unused product immediately.

6.5 Nature and composition of immediate packaging

20g low density polyethylene (white) disposable syringe with high density polyethylene (white) plunger and low density polyethylene (white) cap (push-fit).

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

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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10047/044/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1989

Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

August 2012