1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Equine Granules 22.2 % w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:
Active Substance:
Fenbendazole 222 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Granules.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses and other equines.

4.2 Indications for use, specifying the target species

For the treatment of immature and mature stages of nematodes of the gastro-intestinal and respiratory tracts of horses and other equines.

Sensitive endoparasites include adult and immature (larval) stages of:

Large strongyles
Small strongyles
Ascarids
Oxyuris equi
Dictyocaulus arnfeldi

Panacur is effective for the treatment of migrating strongyle infections and inhibited cyathostome larvae in the large intestine mucosa.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance.

4.4 Special warnings for each target species

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.

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 benzimidazoles has been reported in gastro-intestinal nematodes in horses. Therefore, the use of this product should be based on local epidemiological information about susceptibility of the nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

Special precautions for use in animals

As with other anthelmintics, veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance developing.

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

Direct contact with the skin should be kept to a minimum.Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Can be administered to animals at any stage of pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Administration is by the oral route.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked (if any).

Routine treatment:One sachet per 300 kg bodyweight as a single dose (7.5 mg Fenbendazole/kg bodyweight (each gram of Panacur 22.2% granules contains 222 mg Fenbendazole)).

Weight	**Type**	**Dosage**
Up to 300 kg	e.g. Donkeys, Shetlands, other small ponies, etc.	1 sachet
300-600 kg	e.g. larger ponies, Thoroughbreds, light hunters, Arabs, etc.	2 sachets
600 kg +	e.g. heavy hunters, draught horses	3 sachets

Increased dosing for specific infections
For the treatment of encysted mucosal small redworm larvae, a dosage of 30 mg Fenbendazole/kg should be given. For the treatment of migrating stages of *Strongylus vulgaris* and *S. edentatus* infestations a dosage rate of 60 mg/kg fenbendazole is recommended.Alternatively, for the treatment of migrating large redworm and encysted mucosal small redworm larvae, administer 7.5 mg/kg fenbendazole daily for five days.

Where a heavy infestation of *Dictyocaulus arnfeldi* is present it may be necessary to give 15 mg fenbendazole/kg bodyweight.

It is not necessary to withhold feed before or after treatment. Panacur 22.2% Horse Granules are odourless and tasteless and should be mixed with your horses concentrate or grain feed with the full daily dosage given in one feed.

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

None known.

4.11 Withdrawal period(s)

Meat and offal:14 days.
Milk:Do not use in mares producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics; Benzimidazoles and related substances
ATCvet code: QP52AC13

5.1 Pharmacodynamic properties

Febendazole is an antihelminthic belonging to the benzimidazole-carbamate group. It acts by interfering with the energy metabolism of the nematode.
The antihelmintic affects both adult and immature states of the gastro-intestinal and respiratory nematodes. This antihelmintic efficacy is based on inhibition of the polymerisation of tubulin to microtubuli.

5.2 Pharmacokinetic particulars

Febendazole is only partly absorbed after oral administration and is then metabolised in the liver. Febendazole and its metabolites are distributed throughout the body but the highest concentrations are found in the liver. The elimination of febendazole and its metabolites occurs primarily via the faeces (>90%) and to a smaller extent in the urine and milk. Febendazole is metabolised to its sulfoxide, and then to sulfone and amines.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch
Lactose Monohydrate
Povidone 2500

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Heat sealed sachets of Aluminium/Cellulose Foil coated with polyethylene.Boxes of 10 x 10.2 g sachets.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused product or waste materials should be disposed of in accordance with national requirements.
The product should not enter water courses as this may be dangerous for aquatic organisms.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/113/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1999
Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

October 2016