

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectin 22.75 mg chewable tablets for horses.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One chewable tablet contains:

Active substance:
Ivermectin 22.75 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet.
Dark brown with black and white specks and a round shape.

4 CLINICAL PARTICULARS

4.1 Target Species

Horse.

4.2 Indications for use, specifying the target species

Antiparasitic for the treatment of horses infected with adult and immature stages of the following gastro-intestinal nematodes, lungworms, microfilariae and stomach bots:

Large strongyles

<i>Strongylus vulgaris</i>	adults and 4 th stage larvae (arterial stages)
<i>Strongylus edentatus</i>	adults and 4 th stage larvae (tissue stages)
<i>Strongylus equinus</i>	adults

Small strongyles

<i>Triodontophorus</i> spp.	adults
<i>Triodontophorus brevicauda</i>	
<i>Triodontophorus serratus</i>	
<i>Triodontophorus tenuicollis</i>	
<i>Craterostomum acuticaudatum</i>	adults
<i>Coronocyclus</i> spp.	Adults and intraluminal 4th stage larvae

<i>Coronocyclus coronatus</i>	
<i>Coronocyclus labiatus</i>	
<i>Coronocyclus labratus</i>	
<i>Cyathostomum</i> spp.	adults and intraluminal 4 th stage larvae
<i>Cyathostomum catinatum</i>	
<i>Cyathostomum pateratum</i>	
<i>Cylicocyclus</i> spp.	adults and intraluminal 4 th stage larvae
<i>Cylicocyclus ashworthi</i>	
<i>Cylicocyclus elongatus</i>	
<i>Cylicocyclus insigne</i>	
<i>Cylicocyclus leptostomum</i>	
<i>Cylicocyclus nassatus</i>	
<i>Cylicocyclus radiatus</i>	
<i>Cylicodontophorus</i> spp.	adults and intraluminal 4 th stage larvae
<i>Cylicodontophorus bicoronatus</i>	
<i>Cylicostephanus</i> spp.	adults and intraluminal 4 th stage larvae
<i>Cylicostephanus asymmetricus</i>	
<i>Cylicostephanus bidentatus</i>	
<i>Cylicostephanus calicatus</i>	
<i>Cylicostephanus goldi</i>	
<i>Cylicostephanus longibursatus</i>	
<i>Cylicostephanus minutus</i>	
<i>Gyalocephalus capitatus</i>	adults and intraluminal 4 th stage larvae
<i>Parapoteriostomum</i> spp.	adults and intraluminal 4 th stage larvae
<i>Parapoteriostomum euproctus</i>	
<i>Parapoteriostomum mettami</i>	
<i>Petrovinema</i> spp.	adults and intraluminal 4 th stage larvae

Petrovinema poculatum

Poteriostomum spp. adults and intraluminal 4th stage larvae

Poteriostomum imparidentatum

Poteriostomum ratzii

Pinworms

Oxyuris equi adults and immature stages

Large-mouth stomach worms

Habronema muscae adults and skin larvae

Draschia spp. skin larvae

Ascarids

Parascaris equorum adults, 3rd and 4th stage larvae

Hairworms

Trichostrongylus axei adults

Neck threadworms

Onchocerca spp. microfilariae

Stomach bots

Gasterophilus spp. all larval stages

Lungworms

Dictyocaulus arnfieldi adults and immature stages

Intestinal threadworms

Strongyloides westeri adults

Dermatitis caused by skin larvae of *Habronema* and *Draschia* spp. (summer sores) or by *Onchocerca* sp. microfilariae (skin onchocercosis).

4.3 Contraindications

Do not use in horses weighing less than 60 kg.
Do not use in horses known to be hypersensitive to the active ingredient or any of the excipients.
Keep product away from dogs and cats, danger of toxicity.

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 or misadministration of the product.

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 ivermectin has been reported in *Parascaris equorum* in horses. 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.

Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance developing. In the event that a product is suspected of being ineffective, the animal owner is advised to seek veterinary advice.

4.5 Special precautions for use

Special precautions for use in animals

Vectin is registered for use in horses and should be kept away from other animal species. Intolerance with a fatal outcome may occur in dogs following oral intake of Vectin.

Toxicity in dogs and cats may occur following the intake of ivermectin in this product, if they have access to feeding troughs containing tablets, dropped or discarded tablets or used packaging material.

Ivermectin is toxic to turtles/tortoises.

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

Do not eat, drink or smoke while handling the product.

Wash your hands thoroughly with water and soap immediately after use of the product.

Since this veterinary medicinal product can irritate eyes, any contact with the eyes should be avoided while using the product. If accidental exposure occurs, flush eyes immediately with plenty of water.

In case of accidental ingestion or eye irritation, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Occasionally, some horses heavily infected with *Onchocerca microfilariae* have developed oedema and pruritus following dosing, assumed to be due to the death of large numbers of microfilariae. These signs resolve within a few days but symptomatic treatment may be advisable.

In very rare occasions, colic, diarrhoea and anorexia have been reported post treatment, in particular when there is heavy worm burden. In very rare occasions, allergic reactions such as hyper salivation, lingual oedema and urticaria, tachycardia, congested mucus membranes, and subcutaneous oedema have been reported following treatment with the product.

4.7 Use during pregnancy, lactation or lay

Vectin can be used in pregnant and lactating mares.

Also refer to section 4.11.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Vectin is to be administered orally as a single treatment. The product contains a flavour and will be taken voluntarily by most horses. The product can either be administered by hand, similar to a treat, or mixed with a small amount of feed. It should be ensured that the horse consumes the entire dose.

Vectin can be used in horses with a bodyweight of 60 kg and above. To ensure administration of a correct dose, the body weight should be determined as accurately as possible.

The dose scheme provides for a minimum dose of 0.2 mg ivermectin per kg body weight. One chewable tablet is adequate for the treatment of up to 110 kg body weight. For higher body weights, a corresponding number of chewable tablets should be chosen according to the following dose scheme:

Body weight of the horse (kg):	Number of Vectin chewable tablets to be administered:
60 to 110	1
111 to 220	2
221 to 330	3
331 to 440	4
441 to 550	5
551 to 660	6
etc.	etc.

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

Studies have demonstrated there are no adverse effects when horses are administered up to three times the recommended dose. Mild transitory signs (slowed pupillary light response and depression) have been seen at a dose of 1.8 mg/kg. Other signs seen at higher doses include mydriasis, ataxia, tremors, stupor, coma and death. The less severe sign have been transitory. There is no known antidote but if signs of toxicity appear symptomatic therapy is recommended.

4.11 Withdrawal Period(s)

Meat and offal: 52 Days
The product is not authorised for use in mares producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocides, macrocyclic lactones.
ATCvet code: QP54AA01 Ivermectin

5.1 Pharmacodynamic properties

Ivermectin binds selectively and with a high affinity to glutamate-gated chloride ion channels occurring in invertebrate nerve and muscle cells. This leads to an increased permeability of the cell membrane to chloride ions with hyperpolarisation of the nerve and muscle cells, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The high margin of safety for compounds of this class is attributable to the fact that, in mammals, glutamate receptors in chloride ion channels do not occur; the macrocyclic lactones have a low affinity to other mammalian ligand-gated chloride ion channels and they do not readily cross the blood-brain barrier.

5.2 Pharmacokinetic properties

In the horse, ivermectin is quickly absorbed after oral administration. The maximum plasma concentration (average 81.1 ng/ml) is reached 4h after administration of the recommended dose. This peak falls off gradually to an average level of approximately 1.3 ng/ml over a period of 21 days. The resulting average area under the curve (AUC) is 5128.5 h x ng/ml. Ivermectin and its metabolites are mainly excreted via the faeces; only 1-2 % is excreted via urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Magnesium stearate
Macrogol 3350
Soya-bean oil (stabilised with butylhydroxytoluene)
Glycerol
Sweet apple and molasses flavour
Maize starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

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

Bottle: 3 years

Blister: 22 months

Shelf-life after first opening the bottle: 6 months

6.4 Special precautions for storage

Protect from light.

Store blisters below 25°C.

6.5 Nature and composition of immediate packaging

Cardboard box containing 7 chewable tablets in PVC/aluminium heat-sealed peelable blister.
White HDPE bottle with child-resistant closure containing 60 chewable tablets.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with national requirements. EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.
Do not contaminate surface waters or ditches with the product or used container.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/210/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

6th February 2009

10 DATE OF REVISION OF THE TEXT

April 2011