

B. PACKAGE LEAFLET

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Maximec Horse Oral Paste, 18.7mg/g
Maximec Paard Orale Pasta 18.7mg/g
Maximec Pâte orale pour chevaux
Bimectin Orale Pasta voor Paarden 18.7mg/g

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

LU/NL/UK:

Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland

BE:

Marketing authorisation holder

Cross Vetpharm Group Ltd. - Broomhill Road – Tallaght - Dublin 24 – Ireland

Site responsible for batch release

Bimeda Animal Health Limited,
Unit 2/3/4 Airton Close,
Tallaght, Dublin 24,
Ireland

Distributed By:

(dependent on territory)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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Maximec Pâte orale pour chevaux
Bimectin Orale Pasta voor Paarden 18.7mg/g

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Maximec Horse Paste is ready-to-administer, 18.7mg/g oral paste formulation of ivermectin with apple flavour.

4. INDICATION(S)

For broad spectrum use in parasite control for horses, ponies, mares and foals.

Maximec Horse Paste kills the adult and larval stages of most of the important internal parasites including small redworms, the arterial stages of the large redworms, lungworms and bots with a single dose. Maximec Horse Paste kills the small redworms that are resistant to benzimidazole-based wormers.

Maximec Horse Paste has a wide safety margin. At the recommended rate Maximec Horse Paste can be used in foals, mares, ponies and horses. Mares may be treated at any stage of pregnancy and the fertility of stallions that have been treated has not been affected.

Maximec Horse Paste controls the following horse parasites with one treatment:

Large Redworms: adult and arterial larval stages of *Strongylus vulgaris*, adult and tissue larval stages of *S. edentatus*, adults of *S. equinus*, *Craterstonum acuticaudatum* and *Triodontophorus spp.*

Small Redworms: adult and immature stages including strains that are resistant to benzimidazole-based wormers; *Coronocyclus spp.*, *Cyathostomum spp.*, *Cylicocyclus spp.*, *Cylicostephanus spp.*, *Cylicodontophorus bicornatus*, *Gyalocephalus capitatus*, *Parapoteriostomum spp.*, *Petrovinema poculatum*, *Poteriostomum imparidentatum*.

Pinworms: adult and immature *Oxyuris equi*.

Lungworms: adult and immature *Dictyocaulus arnfieldi*.

Ascarids: adult and immature *Parascaris equorum*.

Stomach worms: *Trichostrongylus axei* and *Habronema muscae*.

Intestinal threadworms: *Strongyloides westeri*.

Cutaneous worms: microfilariae of *Onchocerca spp.*

Bots: mouth and stomach stages of *Gasterophilus spp.*

5. CONTRAINDICATIONS

Maximec Horse Paste has been formulated specifically for use in horses only. Dogs or cats may be adversely affected by the concentration of ivermectin in this product if they are allowed to ingest spilled paste or have access to used syringes.

6. ADVERSE REACTIONS

Some horses have experienced reactions involving cutaneous swelling and itching shortly after treatment. In most such cases, the horses have been diagnosed as carrying heavy infections of *Onchocerca microfilariae*, and it is assumed the reactions were the result of microfilariae dying in large numbers. Although the signs have resolved spontaneously in a few days, symptomatic treatment may be advisable. Consult your Veterinary Surgeon should these signs persist.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Each syringe contains sufficient paste to treat one 600kg horse at the recommended dose rate (200 mcgs of ivermectin per kg of bodyweight).

Each weight marking on the syringe plunger delivers sufficient paste to treat 100kg of bodyweight. Release the knurled ring by making a ¼ turn and slide the ring up the plunger shaft so that the side of the ring nearest the barrel is at the desired weight marking. Turn the knurled ring ¼ turn to lock in place. Make sure the horse's mouth contains no feed. Remove the plastic cap from the tip of the syringe barrel and insert the syringe at the interdental space (the gap between the front and back teeth). Depress the plunger and deposit the paste over the back of the tongue. Immediately raise the horse's head for a few seconds after dosing.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dosage, body weight should be determined as accurately as possible.

For Best Results: All horses should be included in a regular parasite control program, with particular attention being paid to mares, foals and yearlings. Resistance to ivermectin has been reported in *Parascaris equorum* in horses in a number of countries, including 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.

10. WITHDRAWAL PERIOD

Horses should not be slaughtered for human consumption within 21 days of treatment.
Not permitted for use in lactating mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

For animal treatment only.

This veterinary medicinal product does not require any special storage conditions.

12. SPECIAL WARNING(S)

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 tests(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.

Where there is significant tissue damage following *Habronema* infestation, additional medical therapies may be required.

User Warnings

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

Wash hands after use.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container. Dispose of any unused product and empty container in accordance with guidance from your local waste regulation authority

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

(restrictions or conditions regarding supply and use: dependent on territory)

DERIVED FROM NATURALLY OCCURRING SUBSTANCES

Ivermectin, the active ingredient of Maximec Horse Paste is produced from a naturally occurring fungus (*Streptomyces avermitilis*).