LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimax Tabs 150 mg / 20 mg Chewable tablet for Horses
Praziquantel, Ivermectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each chewable tablet contains:
Praziquantel..... 150 mg
Ivermectin ..... 20 mg

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

8 tablets
2 x 8 tablets
12 x 8 tablets
40 x 8 tablets
48 x 8 tablets

5. TARGET SPECIES

Horses

6. INDICATION(S)

Read package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD

Meat and offal: 35 days.
Not permitted for use in horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.
EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container.

12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

13. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC S.A. - 1ère Avenue – 2065 m – L.I.D. – 06516 CARROS - France

15. MARKETING AUTHORISATION NUMBER(S)

16. MANUFACTURER'S BATCH NUMBER

Lot {number}

17. SPECIAL STORAGE CONDITIONS

Use by: ___/___

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Polypropylene tube

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimax tabs 150 mg / 20 mg Chewable tablet for Horses
Praziquantel, Ivermectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Praziquantel..... 150 mg
Ivermectin ..... 20 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

8 tablets

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

Meat and offal: 35 days.
Not permitted for use in horses producing milk for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

9. SPECIAL STORAGE CONDITIONS

Once opened, use within 12 months.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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

Marketing authorisation holder and manufacturer:

VIRBAC S.A. – 1ère Avenue – 2065 m – L.I.D. – 06516 CARROS – France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimax Tabs 150 mg / 20 mg Chewable tablet for Horses

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

Each chewable tablet of 3300 mg contains:

Ivermectin	20	mg
Praziquantel.....	150	mg

White, circular, biconcave tablets with brown spots.

4. INDICATION(S)

For the treatment of mixed cestode, nematode and arthropod infestations, due to adult and immature roundworms, lungworms, bots and tapeworms in horses:

♦ **Nematodes**
Large-strongyles:
Strongylus vulgaris (adult and arterial larvae)
Strongylus edentatus (adult and L4 tissue larval stages)
Strongylus equinus (adult and L4 larval stage)
Triodontophorus spp. (adult)

Small-strongyles:
Cyathostomum (adult and non-encysted mucosal larvae)*: Cylicocyclus* spp*., Cylicostephanus* spp., *Gyalocephalus* spp.

Parascaris: *Parascaris equorum* (adult and larvae).

Oxyuris: *Oxyuris equi* (adult and larvae).
Trichostrongylus: *Trichostrongylus axei* (adult).

♦ **Cestodes (Tapeworm):** *Anoplocephala perfoliata Anoplocephala magna, Paranoplocephala mamillana*

♦ **Dipteran insects**: *Gasterophilus* spp. (larvae).

5. CONTRAINDICATIONS

Do not use in foals under 2 weeks of age.
Do not use in horses known to be hypersensitive to the active ingredients or any of the other ingredients.

The product has been formulated for use in horses only.
Cats, Dogs (especially Collies, Old English Sheepdogs and related breeds or crosses), and also turtles and tortoises may be adversely affected by the concentration of ivermectin in this product if they are allowed to ingest tablets.

6. ADVERSE REACTIONS

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

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

Single oral administration.
200 µg of ivermectin and 1.5 mg of praziquantel per kg of bodyweight corresponding to 1 tablet per 100 kg bodyweight.

Weight	Dosage	Weight	Dosage
Up to 100 kg	1 tablet	501-600 kg	6 tablets
101-200 kg	2 tablets	601-700 kg	7 tablets
201-300 kg	3 tablets	701-800 kg	8 tablets
301-400 kg	4 tablets		
401-500 kg	5 tablets		

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

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, body weight should be determined as accurately as possible.
Once the correct dose has been determined, it should be administered in the following way :
Present the tablet in the palm of your hand. Repeat this gesture until the complete dose has been administered. During the initial administration, the tablet can be combined with a small amount of food or a treat to increase the acceptance by the horse.

In the event that the required dose is not ingested an alternative treatment should be administered. Seek the advice of your veterinary practitioner

The veterinary practitioner should give advice regarding appropriate dosing programmes and stock management to achieve adequate parasite control for both tapeworm and roundworm infestations.

10. WITHDRAWAL PERIOD

Meat and offal: 35 days.
Not permitted for use in horses producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions.
Keep out of the reach and sight of children.
Do not use after the expiry date stated on the box.

Once opened, use the product within 1 year.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the carton.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Young foals, miniature horses and toy breeds weighing less than 50 kg may be unable to ingest tablets. Seek the advice of your veterinary surgeon.
Avermectins may not be well tolerated in non target species. Cases of intolerance are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles and tortoises.
Dogs and cats should not be allowed to ingest spilled tablet or have access to used packaging due to the potential for adverse effects related to ivermectin toxicity.
Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use.
Avoid contact with the eyes. In the event of accidental contact with the eyes, rinse immediately with plenty of water. In case of eye irritation, seek medical attention.
Do not eat, drink or smoke while handling this product.
In the case of accidental ingestion, seek medical advice immediately and show the package leaflet to the physician.

Special warnings for the 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 (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 ivermectin has been reported in *Parascaris equorum* in horses in a number of countries including ones in the EU. Therefore the use of this product should be based on national (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics

The product can be used safely in stallions.

Use during pregnancy, lactation or lay
Equimax tabs can be administrated to horses at any stage of pregnancy or lactation.

Interactions with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by ivermectin.

Overdose

A tolerance study performed in foals with doses up to 5 times the recommended dosage did not show any adverse reactions.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Carton box containing 1, 2, 12, 40 or 48 polypropylene tubes of 8 tablets closed by a child proof cap.
Not all pack sizes may be marketed.