LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eraquell Tabs 20 mg Chewable tablets for Horses
ivermectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each chewable tablet contains:

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)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

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 the package leaflet before use.

10. EXPIRY DATE

EXP : {month/year}
Once opened, use within 12 months.

11. SPECIAL STORAGE CONDITIONS

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

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

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

For animal treatment only

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

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

TUBE OF 8 CHEWABLE TABLETS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eraquell Tabs, 20 mg Chewable tablets for Horses
ivermectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ivermectin ..... 20 mg

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

8 tablets

4. ROUTE(S) OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIOD

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

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP : {month/year}
Once opened, use by.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Eraquell Tabs, 20 mg Chewable tablets for Horses

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

Eraquell Tabs, 20 mg Chewable tablets for Horses

3. STATEMENT OF THE ACTIVE SUBSTANCE

Each chewable tablet of 3300 mg contains:

Ivermectin ..... 20 mg

White, circular, biconcave tablet with brown spots.

4. INDICATION(S)

For the treatment of nematode and arthropod infestations, due to adult and immature roundworms and bots 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).

♦ **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 ingredient or any of the other ingredients.
Do not use in dogs or cats as severe adverse reactions may occur.

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, 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 per kg of bodyweight corresponding to 1 tablet per 100 kg bodyweight.

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

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, bodyweight 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.
Presenting one tablet at a time makes it easier for the horse to accept it, however the administration of multiple tablets at once is also possible.
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 surgeon.

The veterinary surgeon should give advice regarding appropriate dosing programmes and stock management to achieve adequate parasite control for both roundworm and bot 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 condition.
Do not use after the expiry date stated on the box.

Once opened, use the product within 1 year.
Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

Special precautions for use in animals
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 spilled tablets or have access to used packaging. (see 4.3).

User warnings
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 event of accidental ingestion, seek medical advice and show the package leaflet to the physician.

Special warnings for 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. 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.

The product is safe for use in stallions.

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.

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

Safety studies were conducted with a veterinary medicinal product containing praziquantel and the same dose of ivermectin (EQUIMAX oral gel), in mares, stallions and foals.
Administration to mares at 3 times the recommended dosage at 14-day intervals during the whole gestation and lactation periods did not result in any abortion, nor any adverse effect during gestation, at parturition or on the mares general health, nor any abnormality in the foals.
Administration to stallions at 3 times the recommended dosage did not show any adverse effect in particular on the reproductive performances.
Administration to foals with doses up to 5 times the recommended dosage did not show any adverse reaction.

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

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

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 polyethylene child proof cap.
Not all pack sizes may be marketed.