LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

CARDBOARD BOXES, JARS AND SACHETS OF 30 g, 60 g AND 100 g.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equibactin 250 mg/g + 50 mg/g oral powder for horses
Sulfadiazine / Trimethoprim

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:
Sulfadiazine 250 mg
Trimethoprim 50 mg

3. PHARMACEUTICAL FORM

Oral powder

4. PACKAGE SIZE

30 g
60 g
100 g
10 x 5 g
10 x 15 g
10 x 30 g
10 x 60 g
10 x 100 g
20 x 5 g
20 x 15 g
20 x 30 g20 x 60 g
28 x 5 g
28 x 15 g
28 x 30 g
28 x 60 g
105 g
210 g
420 g
840 g

5. TARGET SPECIES

Horses 

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

In feed use
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 20 days
Milk: Not permitted for use in mares producing milk for human consumption.

9. SPECIAL WARNINGS, IF NECESSARY

Sulphonamides may cause severe allergic reactions.

10. EXPIRY DATE

EXP:
Jars: Once opened use within 3 months.
Discard date:
Sachets: Once opened use within 24 hours if stored dry and re-closed with clip (after folding the edge of the opened sachet).
Shelf life after incorporation into meal: use immediately

11. SPECIAL STORAGE CONDITIONS

Keep the sachets and jars tightly closed after first opening in order to protect from moisture.

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

Disposal: read package leaflet.

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

For animal treatment only.
To be supplied only on veterinary prescription.

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

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50406/4009

17. MANUFACTURER'S BATCH NUMBER

Lot.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SACHETS OF 5 g AND 15 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equibactin 250 mg/g + 50 mg/g oral powder for horses
Sulfadiazine / Trimethoprim

2. QUANTITY OF ACTIVE SUBSTANCES

Each gram contains:
Sulfadiazine 250 mg
Trimethoprim 50 mg

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

5 g
15 g

4. ROUTE(S) OF ADMINISTRATION

In feed use
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Meat and offal: 20 days
Milk: Not permitted for use in mares producing milk for human consumption.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:
Once opened use within 24 hours if stored dry and re-closed with clip.
Shelf life after incorporation into meal: use immediately

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

Equibactin vet. 250 mg/g + 50 mg/g oral powder 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:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Manufacturer responsible for batch release:
LelyPharma B.V.
Zuiveringweg 42
8243 PZ Lelystad
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equibactin 250 mg/g + 50 mg/g oral powder for horses
Sulfadiazine / Trimethoprim

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each gram white to off-white powder contains:
Active substances:
Sulfadiazine 250 mg
Trimethoprim 50 mg

4. INDICATIONS

For the treatment of infections in horses caused by micro-organisms susceptible to the combination of trimethoprim and sulfadiazine, such as infections of the upper respiratory tract, the urogenital system and wound infections.

5. CONTRAINDICATIONS

Do not use in horses with severe liver or kidney disease.
Do not use in known cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in known cases of resistance to trimethoprim and sulphonamides.

6. ADVERSE REACTIONS

The following adverse reactions can occur:
- Hypersensitivity reactions such as urticaria
- Inappetence
- Gastrointestinal disturbances such as loose faeces, diarrhoea and colitis
- Hepatic or renal disorders.

- Hematologic effects, such as anaemia, thrombocytopenia, or leukopenia
- Haematuria, crystalluria, tubular obstruction

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses 

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

In feed use

The recommended dose is 30 mg of the active substances together (i.e. 25 mg sulfadiazine and 5 mg trimethoprim) per kg body weight. equivalent to 10 g powder per 100 kg, once or twice daily for 5 days.
Frequency of dosing is decided on basis of the susceptibility of the pathogens involved and location of the infection.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage body weight should be determined as accurately as possible to avoid under dosing. The use of suitably calibrated weighing equipment for the administration of the calculated
amount of the product is recommended when using the jars or parts of the sachets.
The powder can be mixed in a handful of feed immediately prior to dosing. The active ingredients in the powder have a bitter taste. Adding molasses or other sweetener to the feed can facilitate administration of the product. The remaining feed should be withheld until half an hour after the horse has eaten the feed with the medicine.
Should a horse continue to reject the medicated feed, treatment should be continued with another pharmaceutical form with the same actives.

10. WITHDRAWAL PERIODS

Meat and offal: 20 days
Milk:
Not permitted for use in mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions.
Keep the sachets and jars tightly closed after first opening in order to protect from moisture.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging (jars): 3 months

Shelf-life after first opening the immediate packaging (sachets): 24 hours if stored dry and re-closed with clip (after folding the edge of the opened sachet).
Shelf life after incorporation into meal: use immediately

12. SPECIAL WARNINGS

Special precautions for use in animals
Throughout the treatment, animals should have free access to drinking water to avoid possible crystalluria.
In the treatment of new-born animals and animals with liver damage, caution should be exercised.
Renal impairment may cause accumulation, increasing the risk of side effects in long term treatment.
Use the product cautiously in horses with blood dyscrasias.
Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target bacteria at farm level, or at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies Use of the product deviating from the instructions given in this leaflet may increase the prevalence of bacteria resistant to the product, and may decrease the effectiveness of treatment with other antimicrobials or classes of antimicrobials due to the potential for cross-resistance.
In case of infections involving purulent conditions, trimethoprim-sulphonamides combinations are not recommended due to a diminished efficacy under such conditions.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product contains sulfadiazine, a sulphonamide which can cause hypersensitivity reactions following skin contact, inhalation or accidental ingestion. Allergic reactions to sulphonamides may occasionally be serious.
Contact with the veterinary medicinal product should be avoided. This is especially important for people with known hypersensitivity to sulphonamides.
Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator conforming to European Standard EN140 with filter EN143 when handling this product.
Avoid contact with skin. Rubber gloves should be worn when handling this product. In the case of contact with skin, wash with soap and water.
If symptoms develop following exposure such as a skin rash or difficulty with breathing and irritation persists, seek medical advice.
Wash hands thoroughly after use.

Use during pregnancy and lactation
Laboratory studies in rats and mice have shown evidence of teratogenic effects at dosages that are far above therapeutic dosages.
The safety of the veterinary medicinal product during pregnancy and lactation has not been assessed in the target species; use in pregnant or lactating mares should therefore be avoided.

Interactions with other medicinal products and other forms of interaction
Combinations of sulphonamides with trimethoprim used in conjunction with alpha2-

adrenoceptor agonists like detomidine are known to be able to cause fatal arrhythmias in the horse.

Major incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Overdose (symptoms, emergency procedures, antidotes)
The active ingredients in the powder have a bitter taste. Horses will be reluctant to consume medicated feed that is highly overdosed. In case of an overdose loose faeces or diarrhoea may be observed. This is generally self-limiting, but if needed can be treated symptomatically, e.g. fluid therapy in case of dehydration.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS, IF ANY

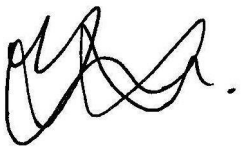
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

White HDPE jars with a LDPE cap containing 105 g, 210 g or 420 g powder.
White PP jars with a LDPE cap containing 840 g powder.
Cardboard boxes containing 10, 20 or 28 aluminum sachets each containing 5 g, 15 g, 30 g or 60 g powder.
Cardboard boxes containing 10 aluminum sachets each containing 100 g powder.

Not all pack sizes may be marketed.



Approved: 28 July 2023