#### **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 vet. 250 mg/g + 50 mg/g oral powder for horses (FR, IS, NO, SE, EE, LT, LV, PL) Equibactin 250 mg/g + 50 mg/g oral powder for horses (AT, BE, BG, CY, DE, EL, ES, HR, HU, IE, IT, LU, NL, PT, RO, SI, SK, UK) 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 13 g

10 x 30 g

10 x 60 g

10 x 100 g

20 x 5 g

20 x 15 g

20 x 30 g

20 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)

## 17. MANUFACTURER'S BATCH NUMBER

Lot.

#### MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACAKAGING UNITS

## SACHETS OF 5 g AND 15 g

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equibactin vet. 250 mg/g + 50 mg/g oral powder for horses (FR, IS, NO, SE, EE, LT, LV, PL) Equibactin 250 mg/g + 50 mg/g oral powder for horses (AT, BE, BG, CY, DE, EL, ES, HR, HU, IE, IT, LU, NL, PT, RO, SI, SK, UK) 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.