

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**CARDBOARD BOX – JAR AND SACHETS****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Equibactin vet. 250 mg/g + 50 mg/g oral powder

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Sulfadiazine 250 mg

Trimethoprim 50 mg

3. PACKAGE SIZE

5 g
15 g
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 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

4. TARGET SPECIES

Horses

5. INDICATIONS**6. ROUTES OF ADMINISTRATION**

In-feed use

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 20 days

Milk: Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Jar: Once opened use within 3 months. Once opened use by...

Sachet: 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

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**JAR (105 g, 210 g, 420 g and 840 g) AND SACHETS (30 g, 60 g AND 100 g)****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Equibactin vet. 250 mg/g + 50 mg/g oral powder

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Sulfadiazine 250 mg

Trimethoprim 50 mg

3. TARGET SPECIES

Horses

4. ROUTES OF ADMINISTRATION

In-feed use

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 20 days

Milk: Not authorised for use in animals producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

Jar: Once opened use within 3 months.

Sachet: 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

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER**9. BATCH NUMBER**

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SACHETS OF 5 g AND 15 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equibactin vet.

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Sulfadiazine 250 mg/g
Trimethoprim 50 mg/g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

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