

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.

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| 8. EXPIRY DATE |
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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

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| 9. SPECIAL STORAGE PRECAUTIONS |
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Keep the sachets and jars tightly closed after first opening in order to protect from moisture.

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| 10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE” |
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Read the package leaflet before use.

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| 11. THE WORDS “FOR ANIMAL TREATMENT ONLY” |
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For animal treatment only.

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| 12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN” |
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Keep out of the sight and reach of children.

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| 13. NAME OF THE MARKETING AUTHORISATION HOLDER |
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| 14. MARKETING AUTHORISATION NUMBERS |
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| 15. BATCH NUMBER |
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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

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|--------------|----------|
| 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