PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON

Trimediazine Plain Oral Powder

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trimediazine Plain Oral Powder

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains: trimethoprim 5% w/w, sulfadiazine 25% w/w

3. PHARMACEUTICAL FORM

Oral powder

4. PACKAGE SIZE

10 x 50g sachets

5. TARGET SPECIES

Horse

6. INDICATIONS

Trimediazine Plain is indicated for use in the treatment of bacterial diseases in horses, including upper and lower respiratory tract infections, alimentary tract infections and infected wounds.

7. METHOD AND ROUTE OF ADMINISTRATION

For oral administration in the feed. To be given at a rate of 30mg combined active ingredients per kg bodyweight. Mix with a small quantity of feed. Each 50g sachet provides a daily dose for a 500kg horse, and may be administered daily or divided and administered at 12 hourly intervals for 5 days. It is recommended that other feed be withdrawn until medicated feed has been consumed. Use immediately following incorporation into feed. Discard any remaining medicated feed..

8. SPECIAL WARNINGS, IF NECESSARY

Do not use in horses with severe liver parenchymal damage, kidney damage, known sulphonamide sensitivity, or in horses with blood dyscrasias or cardiac arrhythmia. Do not exceed 7 days continuous treatment. The use of Trimediazine Plain in horses under 1 year or pregnant mares should be avoided. To avoid the possibility of crystalluria, adequate water intake is essential.

9. USER INFORMATION

Persons handling this product should avoid inhalation of any dust and contact with skin. Wear either a disposable half-mask respirator conforming to European Standard to EN149 or a non-disposable respirator to European Standard to EN140 with filter EN143 when mixing or handling this product. Rubber gloves should be worn when mixing or handling this product. Hands should be washed thoroughly after use. Sulphonamides may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to sulphonamides may lead to cross reactions with other antibiotics. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitive to sulphonamides.
2. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC
Store in a dry place away from animal feeding stuffs.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste authority.

13. WITHDRAWAL PERIOD

Meat: 6 months

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

For animal treatment only.

POM-V	POM

To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

16. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Manufacturer and site of batch release:
Vetoquinol Biowet Sp. z o.o.
ul. Kosynierów Gdyńskich 13-14
66-400 Gorzów Wielkopolski

Marketing Authorisation Holder:
Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

17. MARKETING AUTHORISATION NUMBERS

Vm 08007/4036
VPA 10966/004/001

18. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - SACHET

TRIMEDIAZINE Plain Oral Powder

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trimediazine Plain Oral Powder

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains: trimethoprim 5% w/w, sulfadiazine 25% w/w

3. PHARMACEUTICAL FORM

Oral Powder

4. PACKAGE SIZE

50g

5. TARGET SPECIES

Horse

6. INDICATIONS

Trimediazine Plain is indicated for use in the treatment of bacterial diseases in horses, including upper and lower respiratory tract infections, alimentary tract infections and infected wounds.

7. METHOD AND ROUTE OF ADMINISTRATION

For oral administration in the feed.
To be given at a rate of 30 mg combined active ingredients per kg bodyweight.
Mix with a small quantity of feed. Each 50 g sachet provides a daily dose for a 500 kg horse and may be administered daily or divided and administered at 12 hourly intervals, for 5 days.
It is recommended that other feed be withdrawn until medicated feed has been consumed. Add to feed immediately before administration. Discard any remaining medicated feed.

8. SPECIAL WARNINGS, IF NECESSARY

Do not use in horses with severe liver parenchymal damage or kidney damage or known sulphonamide sensitivity, or horses with blood dyscrasias or cardiac arrhythmias. Do not exceed 7 days continuous treatment.
The use of Trimediazine Plain in horses under 1 year old or pregnant mares should be avoided.
To avoid possible crystalluria, adequate water intake is essential.

USER INFORMATION:
Persons handling this product should avoid inhalation of any dust and contact with skin. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with filter EN143 when mixing or handling this product. Rubber gloves should be worn when mixing or handling this product. Hands should be washed thoroughly after use.
Sulphonamides may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to sulphonamides may lead to cross reactions with other antibiotics.
Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitive to sulphonamides.
2. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.

9. EXPIRY DATE

EXP

10. WITHDRAWAL PERIOD

Meat: 6 months

11. SPECIAL STORAGE CONDITIONS

Store in a dry place away from animal feeding stuffs

Do not store above 25ºC

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste authority.

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

For animal treatment only.

POM-V	POM

To be supplied only on veterinary prescription.
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14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Manufacturer and site of batch release:
Vetoquinol Biowet Sp. z o.o.
ul. Kosynierów Gdyńskich 13-14
66-400 Gorzów Wielkopolski

Marketing Authorisation Holder:
Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBERS

UK only Vm 08007/4036
IE only VPA 10966/004/001

17. MANUFACTURER'S BATCH NUMBER

Lot

Approved: 02 May 2018