

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton Box 8 x 4 g}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coxi Plus, Sulfadimethoxine sodium anhydrous 25% w/w powder for oral solution.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Sulfadimethoxine sodium anhydrous 1000 mg (25% w/w) – excip. ad 4 g.

3. PHARMACEUTICAL FORM

Powder for oral solution.

4. PACKAGE SIZE

8 sachets of 4 g

Each sachet contains 1000 mg sulfadimethoxine sodium

5. TARGET SPECIES

Racing pigeons.

6. INDICATION(S)

Treatment and control of coccidiosis in pigeons.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For complete instructions and warnings: see leaflet.

8. WITHDRAWAL PERIOD

NOT for use in pigeons intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

For complete instructions and warnings: see leaflet.

10. EXPIRY DATE

EXP MM/YYYY

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

Store in a dry place.

Protect from light.

Keep sachet in outer carton.

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

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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 reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Oropharma n.v.
Kappellestraat, 70
BE-9800 Deinze, Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 13058/4002

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {4 g PE/Alu/PE/Paper Sachet (packed per 8)}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coxi Plus, Sulfadimethoxine sodium anhydrous 25% w/w powder for oral solution.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Sulfadimethoxine sodium anhydrous 1000 mg (25% w/w) – excip. ad 4 g.

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

4 g

4. ROUTE(S) OF ADMINISTRATION

Powder for oral solution For complete instructions and warnings: see leaflet.

1 sachet per 2 litres of drinking water.

5. WITHDRAWAL PERIOD

NOT for use in pigeons intended for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP MM/YYYY

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Indications: treatment and control of coccidiosis in pigeons

To be supplied only on veterinary prescription

POM-V

Dispose of any unused product in accordance with guidance from your local waste authority

Keep out of the reach of children

9. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Oropharma n.v.
Kappellestraat, 70
BE-9800 Deinze, Belgium

10. MARKETING AUTHORISATION NUMBER(S)

Vm 13058/4002

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
{120 g Polypropylene Tub Lined with a Polyethylene Bag Closed with a Low
Density Polyethylene Push-Fit Lid}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coxi Plus, Sulfadimethoxine sodium anhydrous 25% w/w powder for oral solution.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Sulfadimethoxine sodium anhydrous 1000 mg (25% w/w) – excip. ad 4 g.

3. PHARMACEUTICAL FORM

Powder for oral solution.

4. PACKAGE SIZE

120 g

5. TARGET SPECIES

Racing pigeons.

6. INDICATION(S)

Treatment and control of coccidiosis in pigeons.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

1 spoonful per 2 litres drinking water.

8. WITHDRAWAL PERIOD

NOT for use in pigeons intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Operator warnings: Cut open the sachet using scissors. Sulphonamides may occasionally cause severe allergic reactions. See package leaflet for full warnings. Wash hands after use.

10. EXPIRY DATE

EXP MM/YYYY

Any medicated water not consumed within 24 hours should be discarded.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Store in a dry place.

Protect from light.

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

Dispose of any unused product in accordance with guidance from your local waste regulation authority. **13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE** [*Distribution category*]

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 reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Oropharma n.v.
Kappellestraat, 70
BE-9800 Deinze, Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 13058/4002

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

PACKAGE LEAFLET FOR:

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

Oropharma n.v.
Kappellestraat, 70
BE-9800 Deinze, Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coxi Plus, Sulfadimethoxine sodium anhydrous 25% w/w powder for oral solution.

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Coxi Plus contains sulfadimethoxine sodium anhydrous 25% w/w, 1000mg per 4g sachet or per level spoonful

4. INDICATION(S)

Coccidiosis in pigeons.

5. CONTRAINDICATIONS

Coxi Plus should not be used in birds affected with kidney diseases.
Coxi Plus must not be used during the breeding period.

6. ADVERSE REACTIONS

No side effects are seen

7. TARGET SPECIES

Coxi Plus is only indicated for use in Racing pigeons.

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

Dissolve one sachet or one level spoonful of Coxi Plus in 2 litres of drinking-water (daily ration for 40 pigeons). A Coxi Plus treatment normally lasts 5 days. In case of severe infection, it is necessary to treat the birds for another 5 days after two weeks. During racing season, it's advisable to administer Coxi Plus prophylactic during 2 or 3 days monthly.

9. ADVICE ON CORRECT ADMINISTRATION

The Coxi Plus solution should be renewed daily.
The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of sulphonamide has to be adjusted accordingly.

10. WITHDRAWAL PERIOD(S)

Coxi Plus must not be used in pigeons intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

Store in a dry place.

Protect from light.

Any medicated water which is not consumed within 24 hours should be discarded.

Keep satchel in outer carton

Keep out of reach of children

12. SPECIAL WARNING(S)

- i) Special precautions for use in animals
During treatment, birds should not be allowed to drink from other sources.
It is advisable not to participate at races during the treatment of the pigeons.
If signs of disease persist or appear consult a veterinary surgeon.

- ii) Special precautions for the person administering the veterinary medicinal product to animals
Persons handling this product should avoid inhalation of any dust and contact with skin. Wear either a disposable half-mask respirator conforming the 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 and exposed skin 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.

For Animal Treatment Only.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product in accordance with guidance from your local waste authority, Dispose of unused medicated water by pouring onto excreta in the loft. Excreta from treated birds should not be spread onto land used for growing crops.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

23rd October 2008

15. OTHER INFORMATION

POM-V To be supplied only on veterinary prescription

Vm 13058/4002

Delivery

1 box containing 8 sachets or a plastic container containing 120 g of powder of Coxi Plus for drinking water medication of pigeons

Approved: 25/08/2017

A handwritten signature in black ink, appearing to read 'J. Berg', is written below the approval date.