SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients
Sulfadimethoxine sodium anhydrous 25% w/w (1000 mg/sachet)

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for oral solution.
Fine, granular, white to light yellow, odourless powder.

4. CLINICAL PARTICULARS

4.1 Target species

Racing pigeons.

4.2 Indications for use, specifying the target species

Racing pigeons: treatment and control of coccidiosis.

4.3 Contra-indications

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

4.4 Special warnings for each target species

Not applicable.

4.5 Special precautions for use

i. Special precautions for use in target 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.

ii. Special precautions to be taken by 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 seed medical advice and show the doctor this warning.

iii. Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

No undesirable effects are seen.

4.7 Use during pregnancy, lactation or lay

Do not administer Coxi Plus to parents which are feeding nestlings.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amount(s) to be administered and administration route

Dissolve one sachet or one spoonful of Coxi Plus in 2 litres of drinking-water (daily dose 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.
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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Sulphonamides have a reasonable margin of safety.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

antiprotozoal medicine belonging to the sulfonamides group.

ATC Vet Code:

QP51AG02

5.1 Pharmacodynamic properties

Sulfadimethoxine is a long-acting sulphonamide. Sulphonamides inhibit the DNA-synthesis of sensitive protozoa and organisms by inhibition of the folic acid synthesis. They compete with para-amino benzoic acid in the synthesis of dihydrofolate, which is an essential co-factor in the synthesis of DNA. Coxi Plus has a coccidiocide effect by elimination of the schizogony.

5.2 Pharmacokinetic particulars

Absorption
Sulfadimethoxine sodium is absorbed fast following the administration via the drinking-water to pigeons. Maximum plasma levels are attained within 3 to 8 hours following administration. In the intestinal lumen, the maximum sulfadimethoxine level is reached 12 hours following the start of treatment.

Distribution
Sulfadimethoxine has a distribution volume of about 0.9 l/kg. Sulphonamides mostly show a high plasma protein binding and a rather low affinity for the tissues.

Metabolism and elimination
Sulfadimethoxine is metabolized in birds prior to excretion. In pigeons, hydroxylation of sulphonamides is more important than acetylation.
The administration of sulfadimethoxine sodium via the drinking-water gives a plasma half life of 6 to 10 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate

6.2 Incompatibilities

This product can not be administered at the same time with antibiotics in the drinking-water. Synergism is reported between trimethoprim and sulfadimethoxine.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after dilution or reconstitution according to directions: 24 hours.

6.4 Special precautions for storage

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.

6.5 Nature and composition of immediate packaging

4 g laminated heat sealed polyethylene/aluminium/polyethylene/paper sachet or 120 g polypropylene tubs lined with a polyethylene bag closed with low density polyethylene push-fit lids. The 120 g tub is supplied with a 4 g polystyrene scoop, which a level spoonful supplies 1000 mg of Sulfadimethoxine sodium anhydrous.

The authorised pack size
1 carton box with 8 sachets of 4 g powder.
1 tub with 120 g powder and a 4 g scoop.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Unused medicated water should be disposed of by pouring onto excreta in the loft. Excreta from treated birds should not be spread onto land used for growing crops.

7 MARKETING AUTHORISATION HOLDER

Oropharma n.v.
70 Kapellestraat
BE-9800 Deinze

8. MARKETING AUTHORISATION NUMBER

Vm 13058/4002

9. DATE OF FIRST AUTHORISATION

Date: 14th August 1997

10. DATE OF REVISION OF THE TEXT

Date: 23rd October 2008