Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribrissen Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

Active Substances

Sulphadiazine	400.0 mg
Trimethoprim	80.0 mg

Excipients

Sodium Metabisulphite (E223)	1.0 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Broiler chickens

4.2 Indications for use, specifying the target species

This product is indicated mainly for the treatment of outbreaks of primary bacterial diseases, but it may also be used for secondary bacterial infections associated with respiratory diseases in broilers and turkeys. It has a high degree of activity against *Escherichia coli*, Salmonella and Pasteurella infections including *E. coli* septicaemia, pullorum disease, fowl typhoid and turkey cholera.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.
Do not use in birds producing eggs for human consumption.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

All other sources of water should be removed during the entire period of treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

None reported.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Dose: The recommended daily dose rate should be 15 mg active ingredients per 1kg bodyweight daily. This may be achieved, for example, by administering the suspension to the flock at the rate of 1 ml per 5 litres (or one gallon) of drinking water daily for six-week-old broilers under average conditions. Treatment should continue for five days.

Administration: By drinking water medication. The suspension disperses on dilution in water and forms a stable solution at dilution rates in excess of 1 in 800. The required dose may be added to the water header tank and the header tanks and troughs must be free of dust, algae or other particulate matter. However, the product is not recommended for use with water proportioner systems.

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

There are no specific recommendations in the case of overdosage.

4.11 Withdrawal Period(s)

Meat: 5 days. Animals intended for human comsumption may be slaughtered from 5 days following the last treatment.

Milk: Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterials for systemic use; Sulfadiazine and Trimethoprim.
ATCvet Code: QJ01EW10.

5.1 Pharmacodynamic properties

The two active ingredients produce a sequential double blockade of bacterial synthesis of folinic acid, giving a level of activity many times greater than either drug alone.

Folates are essential to the bacterial/protozoal cell for multiplication and survival.

- Sulphadiazine prevents the bacterial/protozoal cell from synthesising folic acid.

Trimethoprim prevents the conversion of folic acid to folinic acid in the bacterial/protozoal cell, by inhibiting the bacterial/protozoal enzyme-dihydrofolate reductase

Trimethoprim-sulphonamide therapy was devised to take advantage of the discovery that although all cells use folinic acid in the production of purines, pathogenic bacteria and animal cells differ sharply in two aspects of folate metabolism.

1. Where pathogenic bacteria must synthesise folic acid form paraminobenzoic acid, animal cells incorporate folic acid from the food; animals are not therefore directly affected by sulphonamide therapy, at therapeutic doses.

2. Dihydrofolate reductase is required by all cells for the reduction of folic to folinic acid but Trimethoprim has a much greater affinity for the bacterial enzyme - up to 10,000 times greater - than for the dihydrofolate reductase of the animal cell; at therapeutic levels, trimethoprim blocks folinic acid production in the bacterial cell without interrupting animal folate metabolism.

Because of their sequential action, trimethoprim and sulphonamides potentiate each other, greatly increasing their individual antibacterial effects. The action of this combination is bactericidal, whereas the components used separately are generally bacteriostatic. Potentiation is shown even against bacteria that are generally resistant to one or other of the components.

The in-vitro activity covers most common Gram-positive and Gram- negative bacteria including: *Escherichia coli* and *Salmonella* spp.

5.2 Pharmacokinetic properties

The half lives of Trimethoprim and Sulphadiazine following oral administration to chickens are respectively about 1.7 hours and 2.0 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Hydroxide
Diethanolamine
Sodium Metabisulphite (E223)
Polysorbate 80
Sodium Hydroxide Solution (30%) (for pH adjustment)
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after dilution 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.
Do not freeze.

6.5 Nature and composition of immediate packaging

The product is packed in 200 ml and 1000 ml amber glass bottles.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/261/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT

June 2012