SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Tribrissen 48% Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active constituents	**Mg/ml**
Trimethoprim	80
Sulfadiazine	400

Other constituents	
Sodium metabisulphite (E223)	1

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.
The undisturbed product is cream-coloured amorphous sediment in a clear, pale yellow to brown solution. On agitation, a cream- to brown- coloured aqueous suspension for injection is formed.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, pigs and horses.

4.2 Indications for use, specifying the target species

The product may be used in the treatment of a wide range of diseases and conditions of bacterial origin in cattle, pigs and horses associated with sensitive species of organisms:

Respiratory infections of bacterial origin; urogenital tract infections; alimentary tract infections; other infections such as foul-in-the-foot, severe mastitis, bacterial agalactia of sows, infections of the eye, ear or mouth. It may also be used for antibacterial medication in surgical cases where infection is likely to be present, e.g. with compound fractures and where there is established peritonitis.

4.3 Contraindications

None

4.4 Special warnings for target species

None

4.5 Special Precautions for use

i. Special precautions for use in animals

Do not administer by the intravenous or intra-peritoneal route, as on rare occasions death has rapidly followed injection, especially by the intravenous route.

ii. Special precautions to be taken by the person administering the product

Care should be taken to avoid accidental injection and contact with the skin.
Wash hands after use.

Sulphonamides may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to sulphonamides may lead to cross reactions with other antbiotics. 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.

4.6 Adverse reactions (frequency and seriousness)

Very occasionally there may be a temporary swelling at the site of injection.

4.7 Use during pregnancy, lactation or lay

No special precautions

4.8 Interactions with other medicinal products and other forms of interaction

Concurrent administration with sedatives or anaesthetics is contra-indicated in horses due to risk of cardiac arrhythmia.

4.9 Amounts to be administered and administration route

Agitate gently before withdrawing each dose, avoiding excessive frothing.

Dose: For cattle, pigs and horses the dose is 1ml per 32kg (70lb) bodyweight daily, i.e. equivalent to 15mg active ingredients/kg bodyweight. In cases of severe infection the dose may be increased to 1.5ml per 32kg (70lb) daily i.e. equivalent to 22.5mg active ingredients/kg bodyweight. A single injection

may be sufficient in uncomplicated conditions such as wounds and post-operative infections, but in all severe or complicated infections the dose should be repeated daily for up to 5 days, or until two days after the symptoms resolve, up to a maximum of five consecutive days.

Administration: By intramuscular injection. It is recommended that in cattle and horses not more than 20 ml, and in pigs not more than 10 ml, be injected at any one site.

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

There are no data available on overdosage. The signs described in 4.6 may be seen in cases of overdosage.

4.11 Withdrawal periods(s)

Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under the national horse passport legislation.

Cattle (meat): 34 days

Cattle (milk): 156 hours

Pigs: 28 days

5. PHARMACOLOGICAL PROPERTIES

Sulfadiazine is a bacteriostatic antimicrobial product which acts by blocking the biosynthesis of folic acid, transporter of monocarbonated units, indispensable for the biosynthesis of nucleic acids. This action is a consequence of the structural analogy between the molecule of Sulfadiazine and para-aminobenzoic acid (PABA).

The association with Trimethoprim provides a synergistic effect, particularly potent, which results in bactericidal action. This synergism is the result of the folic acid biosynthesis chain blockage at two different levels; Sulfadiazine at the synthetase dihydropteroate level and Trimethoprim at the reductase dihydrofolate level.

Principal action: The two active ingredients produce a sequential double blockade of bacterial synthesis of folinic acid, giving a level of activity many times greater than that obtained from either ingredient alone.

The *in vitro* activity covers most common Gram-positive and Gram-negative bacteria including: *Actinobacillus* spp., *Actinomyces bovis, Bordetella* spp., *Corynebacterium* and *Arcanobacterium* spp., *Escherichia coli*, *Fusobacterium necrophorum*, *Haemophilus* spp., *Klebsiella* spp., *Listeria monocytogenes*,

Nocardia spp., Pasteurella and *Mannhemia* spp., *Proteus* spp., *Salmonella* spp., *Staphylococcus* spp., *Streptococcus* spp.

ATC Vet Code: QJ01EW10

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium metabisulphite (E223)
Sodium hydroxide
Diethanolamine
Polysorbate 80
Water for Injection

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 first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.
Protect from light.
Following withdrawal of the first dose, use product within 28 days. Discard unused material.

6.5 Nature and composition of immediate packaging

50ml or 100ml multidose amber glass vial.
Outer cartons containing 10 x 100 ml vials.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4593

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30/05/1990

10. DATE OF REVISION OF THE TEXT

Date: June 2012