Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Co-Trimoxazole 24% w/v solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active substances	
Sulfamethoxazole	200.0 mg
Trimethoprim	40.0 mg
Excipients	
Benzyl Alcohol	20.0 mg
Butylhydroxytoluene (E321)	0.1 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear, pale to dark-yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

For the treatment of organisms which are susceptible to sulfamethoxazole/trimethoprim (5:1) and which cause disease in cattle: respiratory, urogenital, gastrointestinal and soft tissue infections. In vitro, it is effective against most common gram-negative and gram-positive bacteria, including :

Escherichia Coli
Pasteurella multocida
P. haemolytica
Salmonella typhimurium
S. dublin
Clostridium perfringens
Corynebacterium pyogenes
Staphylococcus aureus
Streptococcus uberis
Haemophilus somnus

4.3 Contraindications

Co-Trimoxazole 24% is contra-indicated in animals known to be allergic to sulfonamides of trimethoprim.

4.4 Special warnings for each target species

Not applicable.

4.5 Special precautions for use

Special precautions for use in animals
The possibility of potential damage to the kidney or liver or haematopoetic system should be considered.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Special Precautions to be taken by the Person Administering the Product to Animals
Avoid introduction of contamination.
Should any apparent growth or discolouration occur, the product should be discarded.

4.6 Adverse reactions (frequency and seriousness)

Allergic skin reactions and anaphylaxis may occur. Local swelling and pain may occur following I.M. injection, but these are transient.

4.7 Use during pregnancy, lactation or lay

Co-Trimoxazole 24% should not be administered to pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

Indomethacine, phenylbutazone and salicylates raise the blood level of sulfamethoxazol (displacement from protein binding site).

Local anaesthetics such as procaine reduce the activity of sulphonamides due to their structural analogy with para-aminobenzoic acid.

4.9 Amounts to be administered and administration route

15 mg/kg body weight i.e. 1 ml/16 kg body weight once daily by intramuscular injection. Duration of therapy: 5 days.
To ensure a correct dosage bodyweight should be determined as accurately as possible.

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

Co-Trimoxazole 24% has a high therapeutic index. Toxicity symptoms occur therefore seldom.

4.11 Withdrawal Period(s)

Edible tissues from slaughtered animal: 14 days.
Milk: With cows milked twice daily, milk for human consumption may only be taken from 56 hours from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group : Sulfonamides and Trimethoprim.
ATCvet code : QJ01EE01.

5.1 Pharmacodynamic properties

CO-TRIMOXAZOLE 24 % is a combination of two chemotherapeutics. Trimethoprim belongs to the group of the pyrimidines which have a bacteriostatic activity against most common Gram-negative and Gram-positive germs. Sulfamethoxazole belongs to the sulfonamides which act bacteriostatically and it has an antibacterial spectrum similar to that of trimethoprim. The activity of sulfamethoxazole is potentiated by trimethoprim. The best combination *in vivo* is 5:1 (SMX:TMP). The combination of the two compounds act synergistically and bactericidally. The spectrum is broadened by combining the two compounds and the development of resistance is slowed down.

5.2 Pharmacokinetic properties

Trimethoprim and sulfamethoxazole are resorbed quickly and completely from the injection site. The maximum plasma concentration is reached within 1 to 2 hours. Trimethoprim is better distributed in tissues and organs than sulfamethoxazole, but this is compensated by the combination of 5 parts of sulfamethoxazole for 1 part of trimethoprim. The highest concentrations are reached in the kidneys, the lungs and the liver. Both components are bound for ca. 50 % to plasma proteins. They are mainly excreted in the urine. Based on the similarity of the pharmacokinetic profile of both components, it is a pharmacokinetically good combination.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Ethanolamine
Butylhydroxytoluene
N-Methylpyrrolidone

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 14 days.

6.4 Special precautions for storage

Store in the refrigerator (2 - 8°C).
Protect from light.

6.5 Nature and composition of immediate packaging

Round type II amber glass vials of 100 ml with bromo butyl rubber stopper, sealed with aluminium cap.

The vials are packed in a polystyrene box, 12 vials of 100 ml per box, with 12 package leaflets.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Kela N.V.
St. Lenaartseweg 48
2320 Hoogstraten
Belgium

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10981/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT

June 2012