1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Co-Trimoxazole 240 mg/ml solution for injection for cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Sulfamethoxazole 200.0 mg
Trimethoprim 40.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol	20.0 mg
Butylhydroxytoluene (E321)	0.1 mg
Ethanolamine	
N-Methylpyrrolidone	Up to 1.0 ml

A clear, pale to dark-yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 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 typhimurcium
S. Dublin
Clostridium perfringens
Corynebacterium pyogenes
Staphylococcus aureus
Streptococcus uberis
Haemophilus somnus

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal product to animals:
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.
Avoid introduction of contamination.
Should any apparent growth or discolouration occur, the product should be discarded.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle

Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site swelling, injection site pain[1]
Rare (1 to 10 animals / 10,000 animals treated):	Allergic skin reaction, anaphylaxis

[1]Transient

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not use the veterinary medicinal product during pregnancy.

3.8 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.

3.9 Administration routes and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The veterinary medicinal product has a high therapeutic index. Toxicity symptoms occur therefore seldom.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal period(s)

Meat and offal: 14 days.
Milk: With cows milked twice daily, milk for human consumption may only be taken from 56 hours from the last treatment.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01EE01

4.2 Pharmacodynamics

The veterinary medicinal product 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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3. Special precautions for storage

Store below 25°C.
Protect from light.

5.4 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Kela n.v.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10981/001/001

8. DATE OF FIRST AUTHORISATION/

01/10/1988

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

11/06/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).