Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Taneven LC 3 g intramammary suspension for cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 intramammary syringe (20 g) contains:

Active substance:

Benzylpenicillin (procaine) monohydrate (equivalent to 1.7 g benzylpenicillin)	3 g

Excipients:

Procaine hydrochloride	0.20 g
Sodium metabisulfite	0.02 g

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension
White to off-white homogenous suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (lactating cows)

4.2 Indications for use, specifying the target species

Treatment of clinical mastitis caused by benzylpenicillin-susceptible streptococci and staphylococci in lactating cows.

4.3 Contraindications

Do not use in cases of
- infections with ß-lactamase producing pathogens
- hypersensitivity to penicillins, other beta-lactam antibiotics or to any of the excipients.
- severe renal dysfunction with anuria or oliguria

4.4 Special warnings for each target species

In case of mastitis with systemic clinical signs, additionally an appropriate parenteral antimicrobial should be administered. Particular attention should be paid to *Staphylococcus aureus* udder infections, which require to distinguish between acute and chronic udder infections prior treatment. Culling of animals which have been identified to suffer from chronic *Staphylococcus aureus* udder infections might be preferred over treatment.

4.5 Special precautions for use

Special precautions for use in animals
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. Official, national and regional antimicrobial policies should be taken into account when the product is used.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to benzylpenicillin and may decrease the effectiveness of treatment with other beta lactam antimicrobials (penicillins and cephalosporins) due to the potential for cross-resistance.

The feeding of waste milk containing residues of penicillin to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.
Care must be taken when applying the product in case of severe udder quarter swelling, milk duct swelling and/or congestion of detritus in the milk duct. Treatment should only be discontinued early after consultation with the veterinarian as this could lead to the development of resistant bacterial strains.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.
People with known hypersensitivity to penicillins should avoid contact with the veterinary medicinal product. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
Handle this product with great care to avoid exposure by accidental contact with skin or eyes. Persons developing a reaction after contact with the product should avoid handling the product and other penicillin and cephalosporin containing products in future.
Wash exposed skin after use. In case of eye contact, wash the eyes thoroughly with copious amounts of clean running water. If you develop symptoms such as a skin rash following exposure, seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention. Wash your hands after use.

4.6 Adverse reactions (frequency and seriousness)

Allergic reactions (allergic skin reactions, anaphylaxis) are to be expected in animals which are sensitive to penicillin and/or to procaine. As the product contains povidone, rare cases of anaphylactic reactions may occur in cattle.
The animal should be treated symptomatically if an adverse reaction occurs.
The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interactions

The effect of aminoglycosides can be enhanced by penicillin.
Elimination of benzylpenicillin is prolonged by acetylsalicylic acid.
There is a potential antagonism to antibiotics with a rapid onset of bacteriostatic effect.
Do not administer concurrently with antibiotics that have a bacteriostatic mode of action.
Combinations with other medicines for intramammary use should be avoided because of possible incompatibilities.

4.9 Amounts to be administered and administration route

Intramammary use.
Administer the content of one syringe (20 g) in each affected udder quarter. The duration of treatment is 3 days, with 24 hour intervals between treatments. If there is no significant improvement after 2 days of treatment, the initial diagnosis should be reassessed and the treatment changed accordingly.
Before administering the intramammary syringe, carefully milk the affected udder quarter and clean and disinfect the teat. Shake well before use.

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

Following overdose central nervous system symptoms and seizures may occur. In these cases discontinue the use of the product immediately and begin supportive and symptomatic treatment.

4.11 Withdrawal period(s)

Meat and offal 5 days
Milk 120 hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Beta-lactame antibiotics, penicillins, for intramammary use
ATC vet code: QJ51CE09.

5.1 Pharmacodynamic properties

The depot-penicillin benzylpenicillin procaine is hardly water-soluble. In the organism, benzylpenicillin and procaine are released by dissociation. The free benzylpenicillin is primarily effective against gram-positive pathogens. Penicillin has a bactericidal effect on proliferating bacteria by inhibition of cell wall synthesis. Benzylpenicillin is acid-unstable and is inactivated by beta-lactamases. The most frequent mechanism of resistance is production of beta-lactamases. Modification of penicillin-binding proteins with reduced affinity to the drug or reduced bacterial permeability represents another and sometimes concomitant mechanism of intrinsic and acquired resistance.
The penicillin-breakpoint proposed in 2018 by CLSI (Clinical and Laboratory Standards Institute, document VET08) can be summarised as follows (human-derived data):

	Clinical Breakpoints		
	Susceptible	**Intermediate**	**Resistant**
Staphylococcus spp. (e.g. *S. aureus; coagulase-negative staphylococci)*	≤0.12 µg/ml	-	≥0.25 µg/ml
Streptococci viridans group (e.g. *S. uberis*)	≤0.12 µg/ml	0.25– 2 µg/ml	≥ 4µg/ml
Streptococci beta-haemolytic group (e.g. *S. dysgalactiae* and *S. agalactiae*)	≤ 0.12 µg/ml	-	-

5.2 Pharmacokinetic particulars

Benzylpenicillin is partially absorbed from the udder following intramammary use. Only the non-dissociated penicillin ions enter the serum as a result of passive diffusion. As benzylpenicillin is strongly dissociated, only very low serum levels occur. One part (25%) of the intracisternally applied benzylpenicillin becomes irreversibly bound to milk and tissue protein. Following intramammary use, benzylpenicillin is largely secreted unchanged via milk from the treated udder quarter, to a small extent via milk from the untreated quarters and also via the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Procaine hydrochloride
Sodium metabisulfite
Lecithin
Sodium citrate
Microcrystalline cellulose and carmellose sodium
Povidone
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.
Naturally occurring penicillins are incompatible with metal ions, amino acids, ascorbic acid and the vitamin B-complex.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Syringes are for single use only.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

Intramammary syringe composed of an injector body made of LDPE or HDPE, a plunger and a cap made of LDPE.
Cardboard box containing 10, 12, 20 or 80 syringes. Each syringe contains 20 g intramammary suspension.
Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

WDT - Wirtschaftsgenossenschaft deutscher Tierarzte eG
Siemenstr. 14
30827 Garbsen
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10660/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 July 2020

10 DATE OF REVISION OF THE TEXT