1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blu-Gard 2.00% w/w Teat Dip Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition	Quantitative composition
Active Substance:	
Linear Dodecylbenzene Sulphonic Acid (97%)	2.00% w/w
Excipients:	
Amaranth (E123)	0.0009% w/w
Patent Blue V (E131)	0.006% w/w
Other Relevant Constituents:	
Glycerol	3.66% w/w
Sorbitol Solution 70%	11.30% w/w

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Teat Dip solution.
A clear blue liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, dairy cows.

4.2 Indications for use, specifying the target species

Post milking teat dip as an aid in the control of mastitis in cattle.

4.3 Contraindications

None.

4.4 Special warnings for each target species

For external use only.

4.5 Special precautions for use

i. Special precautions for use in animals

Wash and dry udders and teats thoroughly preferably with an individual paper towel just before milking.
If the product in the teat dip cup becomes visibly dirty, discard the contents and refill with fresh solution.
Empty teat dip cups after milking and wash them before re-use.
Do not mix with any other product.
Do not return any used product to the original container.
Although Blu-Gard contains emollients it is not sold as cure for badly chapped or inflamed teats. If this condition exists a veterinarian should be consulted.

ii. Special precautions for the person administering the veterinary medicinal product to animals

Avoid contact with skin and eyes.
In case of accidental contact, wash the affected area with plenty of clean running water and seek medical attention if irritation persists.
People who are allergic to ingredients in the product should handle the product with great care (e.g. by wearing rubber gloves).
Wash hands after use.
Do not eat, drink or smoke whilst using this product.
Keep away from food, drink and animal feedstuffs.

iii. Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

The product is indicated specifically for use during lactation. No residues have been detected in milk. As no absorption has been detected from skin no effects on reproduction or on the foetus would be expected nor have they been observed.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

Immediately after milking dip each teat by submerging the entire teat in full strength, undiluted Blu-Gard. Approximately 8ml of Blu-Gard per cow per milking should be used. Allow teats to air dry. Do not wipe. Just prior to next milking wash entire udder and teats thoroughly preferably with an individual paper towel.

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

Not applicable.
Visual identification of dipped teats is facilitated by the inclusion of dyes in the product.
No adverse effects of repeated dipping would be expected as absorption through skin is negligible.
The product does not require dilution therefore application of Blu-Gard at excessive concentrations is not possible.

4.11 Withdrawal period(s)

Cattle: Meat – zero days
Milk – zero hours

5. PHARMACOLOGICAL PROPERTIES

ATCvet Code: QG52A

5.1 Pharmacodynamic properties

The active ingredient of Blu-Gard, sodium dodecylbenzene sulphonate, is an anionic surfactant, bactericidal against Gram-positive and Gram-negative organisms with maximum activity in acid solution. The exact mechanism of its antibacterial action is not fully elucidated but dissolution of the cell wall and lysis of the phospholipid material of the protoplasmic membrane with disorganisation of the permeability barrier of the cell is involved. This results in cytological damage and leakage of metabolites.
Sodium hydroxide and citric acid are included as a citric acid/citrate buffer to maintain the pH in the acid range of 2.8 to 3.2 (optimum pH 3).
Glycerine and Sorbitol act as emollients. They soothe, smooth and hydrate the skin. They form an occlusive film on the stratum corneum and prevent drying from evaporation of water which has diffused from the underlying layers of skin. Glycerol is extensively used as a vehicle for drugs applied to the skin.
Patent Blue V (E131) and Amaranth (E123), food grade dyestuffs, are included to colour the product and identify its presence on teats.
Carmellose is included as a thickener to increase persistence of the product on the surface of the teat and prolong the availability there of the antibacterial action of the product.

5.2 Pharmacokinetic properties

Penetration of anionic surfactants through skin is poor. No penetration of rat skin or of human skin up to 24 hours after application has been detected.
Alkyl benzene sulphonates (including dodecyl benzene sulphonate) are readily absorbed from the intestinal tract of mammals, metabolised to sulphophenyl carboxylic acids and excreted in bile and urine.

5.3 Environmental properties

None.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Sorbitol solution 70%
Patent Blue V (E131)
Amaranth (E123)
Carmellose sodium
Sodium hydroxide
Citric acid, anhydrous
Water, softened

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Store away from food, drink and animal feedstuffs.
Protect from frost.
Store in tightly closed original containers.

6.5 Nature and composition of immediate packaging

Pack size: 20 L:
Container: Opaque white high-density polyethylene (HDPE) drums.
Closures: Opaque high-density polyethylene (HDPE) caps.
Pack size: 200 L:
Container: Opaque blue high-density polyethylene (HDPE) drums.
Closures: 2x high-density polyethylene (HDPE) bungs (in internally threaded neck).
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, if appropriate

Harmful to aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.
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

Ecolab Ltd
Lotherton Way, Garforth
Leeds
LS25 2JY
UK

8. MARKETING AUTHORISATION NUMBER

VM 04509/4005

9. DATE OF FIRST AUTHORISATION

Date: 29.04.1992

10. DATE OF REVISION OF THE TEXT

Date: December 2008