

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Alcide UDDERgold Platinum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The Base concentrate contains:

Active substance:

Sodium chlorite	6.4	mg/ml
(equivalent to chlorous acid	4.84	mg/ml)

Excipient:

Disodium edetate dihydrate	1.9	mg/ml
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The Activator concentrate contains:

Active substance:

Lactic acid	26.4	mg/ml
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Excipients:

Sodium benzoate (E211)	2.0	mg/ml
Tartrazine (E102)	3.0	mg/ml

Each ingredient is present in the 1:1 mixture at one half the stated concentrations immediately after mixing. For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Teat dip concentrates ("Base" and "Activator") for teat dip solution.

Base concentrate is a viscous clear/white solution.

Activator concentrate is a viscous yellow solution.

Base and Activator, when mixed 1:1, form a gold solution for teat use.

4 CLINICAL PARTICULARS

4.1 Target Species

Dairy cows.

4.2 Indications for use, specifying the target species

A post-milking teat dip for use as an aid in the control of mastitis in dairy cows caused by pathogens such as *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis* or *Escherichia coli*.

4.3 Contraindications

Do not use on traumatized or inflamed teats.

Discontinue use in any cow showing signs of irritation or hypersensitivity to the product.

Not for use in sanitising dairy equipment.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

For external use only. Prior to milking, wash teats thoroughly with water or a compatible udder wash using proper procedures and dry before milking. Do not turn cows out in freezing weather until teat dip is completely dry. Drying takes approximately 8 - 20 minutes under these conditions. If signs of disease persist or appear, consult your veterinary surgeon.

Special precautions to be taken by the person administering the product to animals

Wash hands after use.

Use in a well-ventilated area as there is a possibility of a build up of irritating chlorine dioxide gas.

Irritating to eyes. Avoid contact with eyes. If contact occurs, flush eyes with large quantities of water. See a doctor if irritation develops.

In the event of accidental exposure, remove by dilution, i.e.:

External: wash with water;

Ingestion: drink water;

Inhalation: remove to fresh air

4.6 Adverse reactions (frequency and seriousness)

Irritation of teats occurs infrequently; it largely depends on the hygiene procedures, i.e. whether residues are effectively removed prior to milking. If residues from the teat dip are allowed to build up, a dry crust may form. Removal of such crust may leave the teat skin sore and irritated.

4.7 Use during pregnancy, lactation or lay

Indicated for use in lactating dairy cows. See Section 4.11 for withdrawal periods.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For topical use as a teat dip. Mix together equal volumes of the Activator and Base until the colour is uniform throughout. The gold colour in the mixed product may fade with time and this may be more rapid at higher temperatures. This does not affect the efficacy of the product.

Wash and dry udders and teats before milking. Immediately **after** milking dip all teats at least one half their length in the mixed product. Allow to air dry before cows are turned out to pasture, especially in freezing weather. Do not wipe. On average, approximately 7.5ml of product will be used per cow per milking. Always use freshly mixed, full strength Alcide UDDERgold Platinum.

Prior to the next milking, wash teats thoroughly with a compatible udder wash using proper procedures.

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

Not applicable.

4.11 Withdrawal period(s)

Cattle: Meat – zero days

Milk – zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Products for teats and udder, disinfectants.

ATC vet code: QG52A

5.1 Pharmacodynamic properties

When the chlorite active ingredient in the Base is activated by acidification with the lactic acid in the Activator, a germicidal system is formed in equilibrium with the chlorite and consisting of short-lived chlorous acid and its related oxychlorine disproportionation products.

+H⁺
 $\text{ClO}_2^- \leftrightarrow \text{HClO}_2 \rightarrow$ antimicrobial oxychlorine species
 chlorite -H⁺ chlorous
 acid

Lactic acid →→ antimicrobial species

The chlorous acid/derived species system has a highly potent and broad spectrum of germicidal activity, probably via oxidative attack at susceptible sites on the microbial envelope.

The lactic acid (excess) exerts its antimicrobial effect by adsorbing to cell surfaces and promoting leakage of hydrogen ions across the cell membrane, resulting in the acidification of the cell interior and inhibition of nutrient transport.

In vitro efficacy of the UDDERgold barrier teat dip system was studied using excised cows teats artificially contaminated with cultures of mastitis-causing organisms. The chlorous acid/oxychlorine antimicrobial system was found to be effective against *Staphylococcus aureus*, *Streptococcus agalactia*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, *Klebsiella pneumonia*, *Escherichia coli*, *Pseudomonas aeruginosa* and *Listeria monocytogenes*.

A gel forming material (polysulfonic acid) has been incorporated into the formulation to ensure that once the initial germicidal activity of the acidified chlorite system has been exhausted, the disinfected skin surface and particularly the teat end and teat canal are effectively enclosed and protected by a film, thereby preventing further recontamination. In addition, the film entraps residual lactic acid left over from the initial chemical reaction.

5.2 Pharmacokinetic particulars

Not applicable.

6 PHARMACEUTICAL PARTICULARS**6.1 List of excipients****Base:**

Disodium edetate dihydrate
 Polysulfonic acid
 Sodium hydroxide
 Water purified

Activator:

Sodium benzoate (E211)
 Tartrazine (E102)
 Hydroxyethyl cellulose
 Glycerol
 Sodium dodecylbenzene sulfonate
 Water purified

6.2 Major incompatibilities

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

6.3 Shelf-life

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

Base: 2 years

Activator: 2 years

Shelf life of the ready-to-use solution (1:1 mixture of Base and Activator): 3 hours

A fresh solution should be prepared immediately **before** use and be used within 3 hours. Any unused material should be discarded.

6.4 Special precautions for storage

Protect from light. Do not freeze*.

Store in tightly closed original container.

Store away from food, drink, and animal feedstuffs.

*Freezing will not affect the performance of the product provided that the frozen contents are thawed completely and agitated thoroughly before mixing the Base and the Activator components.

6.5 Nature and composition of immediate packaging

Base and Activator are supplied separately, packed in pairs of high density polyethylene (HDPE) bottles/containers with polypropylene or HDPE screw caps holding 3.785, 10 or 20 litres of the Base or Activator component.

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

Ecolab Deutschland GmbH

Ecolab-Allee 1

40789 Monheim am Rhein

Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10795/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 April 2008

Date of last renewal: 10 September 2009

10 DATE OF REVISION OF THE TEXT

April 2013