Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Agrisept MC Tabs 2.5g effervescent tablet for teat dip/spray solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 g tablet contains:

Active substance:
2.5g Sodium Dichloroisocyanurate

Excipients: For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Effervescent tablet for teat dip/spray solution.
White/off white, flat beveled edged effervescent tablet with stag emboss.

4 CLINICAL PARTICULARS

4.1 Target Species

Lactating Dairy Cattle and the minor species Sheep and Goat.

4.2 Indications for use, specifying the target species

Control of mastitis in lactating Dairy Cattle and lactating Sheep and Goats.
Aid in the healing of lesions of teats and udders.

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Use freshly prepared solutions. For reasons of farm safety it is recommended that Agrisept MC Tabs stock solutions be stored for up to 7 days in a secure place, away from direct sunlight.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Protection of Operators: The use of Agrisept MC Tabs, as directed, should not present a hazard to man. In case of contact with eyes, irrigate with plenty of water and if necessary obtain medical advice. In the case of ingestion, an upset stomach may result, which may be remedied by milk given orally but if necessary obtain medical advice. Take care – Agrisept can bleach fabrics.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product is intended for use on the udder/teats of lactating dairy cattle, and by extrapolation, lactating sheep and goats, pre- and post-milking.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Depending on the intended use of the product, Agrisept MC Tab tablets should be reconstituted with water in accordance with the following table:

Usage Chart	No. Tablets	No. Litres Water
Before Milking		
1. Pre-Milk Udder/Teat Wash		
a) During Mastitis Outbreak	1	1
b) Routine Mastitis Prevention	1	10
2. Milker's Hand Wash	1	10
3. Pre-milk Teat Spray	1	1
4. Pre-milk Teat Dip		
a) During Mastitis Outbreaks	2	1
b) Routine Mastitis Prevention	1	1
Usage Chart	No. Tablets	No. Litres Water
After Milking		
1. Post-Milk Teat Spray	1	1
2. Post-Milk Teat Dip		
a) During Mastitis Outbreaks	2	1
b) Routine Mastitis Prevention	1	1
3. Cluster Dip		
a) Between Cows	1	10
b) At end of milking	1	10
4. Utensil Scrub/Rinse	1	10
5. Milker's Hand Wash	1	10

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

No adverse reactions have been observed in animals treated for a period of 56 days at 4 times the maximum recommended dose rates.

4.11 Withdrawal Period(s)

Meat and offal: 0 days.
Milk: 0 hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Disinfectant for the control of mastitis and as an aid in the healing of lesions of teats and udders.
ATCVet code: QG52A

5.1 Pharmacodynamic properties

When dissolved in water, sodium dichloro-isocyanurate (NaDCC) dissociates to give hypochlorous acid in equilibrium with cyanurate. The antibacterial action of the product results from the oxidation of cell constituents with the ionized hypochlorous acid molecule. Solutions of NaDCC have been shown to be effective against a variety of bacteria including: Streptococci, *Escherichia coli*, *Corynebacterium pyogenes*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella typhimurium*.

5.2 Pharmacokinetic properties

There is no evidence of pharmacologically relevant absorption of NaDCC or its metabolites from intact skin or from wounds or other skin lesions.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Adipic Acid
Sodium Hydrogen Carbonate
Sodium Carbonate anhydrous

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after reconstitution according to directions: 7 days.

6.4 Special precautions for storage

Tubs: Store below 25°C. Store in a dry place. Keep the tub firmly closed. Protect reconstituted solution from direct sunlight.
Foil pack: Store below 25°C. Store in a dry place. Protect reconstituted solution from direct sunlight.

6.5 Nature and composition of immediate packaging

Tubs: The product is packed into a polypropylene container with a wadless low density polyethylene lid and polyethylene foam wadding (Plastazote). 100 tablets per tub.

Foil Pack: Tablets are strip packed in aluminium foil laminate strips packed in cartons of 50 and 100 tablets in strips of 10.

Not all pack sizes may be marketed.

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

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

Medentech Ltd.
Whitemill Industrial Estate
Clonard Road
Wexford
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10928/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17th December 2008

10 DATE OF REVISION OF THE TEXT

29th June 2011