IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10808/001/001**
Case No: 7001476

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

John Godfrey

Ferrybridge, **Clarina**, **Co. Limerick**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Masticare

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

Signed on behalf of the Irish Medicines Board this

_____

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Masticare

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active:

Chlorhexidine gluconate (As Chlorhexidine digluconate 20% w/v solution)	0.5 %w/v

Excipients:

Glycerin	6.00 %w/v
Isopropyl Alcohol	4.00 %w/v
Carmoisine (E122)	0.005 %w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Teat dip/spray.

4 CLINICAL PARTICULARS

4.1 Target Species

Lactating Dairy Cows

4.2 Indications for use, specifying the target species

As an aid for the control and prevention of mastitis in lactating dairy cows, by dipping or spraying the cows teats.

4.3 Contraindications

Do not use in case of known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

Spray or dip the entire surface of each teat.

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

Rinse splashes in the eyes with water. Avoid working in a spray mist. In case of accidental ingestion, consult a physician.

4.6 Adverse reactions (frequency and seriousness)

Irritative skin reactions can occasionally occur. Generalised allergic reactions to chlorhexidine have been reported but are extremely rare.

4.7 Use during pregnancy, lactation or lay

It is safe to use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not mix with other chemicals. Incompatible with soaps and other anionic materials. Cork closures must not be used for containers.

4.9 Amounts to be administered and administration route

Masticare is used undiluted as a teat dip after milking.
Teat dipping:
Pour teat dip into teat cups. Dip teats of every cow immediately after milking, ensuring that the full length of each teat is dipped. Refill the cup as necessary. Teat dip cups should be emptied after milking and washed before re-use.
Teat spraying:
Spray the full length of each teat after milking, ensuring that the entire surface of each teat is covered.
Wash and dry teats and udders before next milking.

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

None known.

4.11 Withdrawal Period(s)

Meat: zero days.
Milk: zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

An antiseptic and bactericidal disinfectant used as an aid for the control and prevention of mastitis in lactating dairy cows.
The active ingredient, Chlorhexidine, is a cationic surfactant belonging to the biguanidine group of cationic surfactants, which is active against both gram positive and gram negative organisms and acts by disrupting cellular matter.

5.1 Pharmacodynamic properties

The pharmacodynamics of chlorhexidine digluconate show that it is a highly active antiseptic against gram-positive and gram-negative organisms. The mode of action involves adsorption to phosphate compounds on the bacterial surface causing leakage and precipitation of cytoplasm leading to cell death.
It has been suggested that chlorhexidine damages the permeability barrier of the bacterial cell and subsequently blocks electron transport in the cytochrome system. Thus this compound penetrates the cell wall by overcoming the exclusion mechanism and is then attracted towards the cytoplasmic components. This causes leakage of low molecular weight cytoplasmic components and precipitation of the cytoplasm by the formation of complexes with phosphates moieties leading to cell death.
The activity of chlorhexidine is well maintained in the presence of tissue fluids and pus and in the presence of other antiseptics such as quaternary ammonium compounds but is incompatible with anionic compounds (e.g. iodine, chlorine, and soaps).

5.2 Pharmacokinetic properties

Chlorhexidine binds strongly to the skin and mucosa because of its cationic nature. It is therefore poorly absorbed after oral or topical application.
Aqueous solutions of chlorhexidine salts decompose to produce trace amounts of 4-chloroaniline. This decomposition is increased by heating and alkaline pH conditions.
Studies were carried out on percutaneous absorption in the human following administration of 4% chlorhexidine in a formulated product and a 5% formulated hand wash product. After three hours, the amount recovered in urine or faeces was very low with only traces of chlorhexidine being found in faeces and with nothing being detected in urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone K 30
Octylphenoxy polyethoxyethanol
Glycerin
Isopropyl Alcohol
Carmoisine (E122)
Purified Water

6.2 Incompatibilities

Chlorhexidine is a cationic surfactant and therefore incompatible with soaps and other anionic detergents. Do not mix with any other chemicals or other teat dips e.g. iodine containing teat dips.

6.3 Shelf-life

Three years.

6.4 Special precautions for storage

Do not store above 25°C. Keep container upright and tightly closed

6.5 Nature and composition of immediate packaging

5 litre and 25 litre capacity, high density polypropylene containers.

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

Unused material should not be poured down the drain but disposed of safely in accordance with National Waste Regulations.
Do not contaminate ponds, waterways and ditches.

7 MARKETING AUTHORISATION HOLDER

John Godfrey
Ferrybridge
Clarina
Co. Limerick

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10808/1/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5th April 2002

10 DATE OF REVISION OF THE TEXT

18th June 2004