

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10880/002/001**

Case No: 7006032

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Ecolab Ltd.

La Vallee House, Upper Dargle Road, Co. Wicklow, 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:

N.C.F. Teat Dip 0.5 %w/v

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.

The authorisation, unless previously revoked, shall continue in force from **30/09/2009**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

N.C.F. Teat Dip 0.5% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Complexed Iodine

(equivalent to available iodine) 0.5 % w/v

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Teat dip

A clear dark brown solution

4 CLINICAL PARTICULARS

4.1 Target Species

Lactating bovines.

4.2 Indications for use, specifying the target species

For use in cows as a teat dip, teat spray and udder wash, as an aid in the control of mastitis and teat chapping. For maintaining the teat skin in a supple and smooth condition.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient 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:

Before milking, teats should be washed and thoroughly dried, preferably with an individual paper towel. Teat dip cup should be emptied after milking and washed before re-use.

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

If the milker is allergic or idiosyncratic towards iodine it is recommended to change to a non-iodine based product. Do not breathe spray.

FIRST AID:

Ingestion: Do not induce vomiting. If ingested, give copious draughts of milk or water.

Skin Contact: Wash with water.

Eye Contact: Irrigate with water and seek medical aid.

Inhalation: If affected by vapour, remove to fresh air. Keep at rest and keep warm. Seek medical aid.

Guide To Doctor:

Symptoms of poisoning may include metallic taste, abdominal pain, vomiting and diarrhoea. The stomach should be emptied by emesis or gastric lavage. Treat as for iodine ingestion.

4.6 Adverse reactions (frequency and seriousness)

Iodophor teat disinfectants can be regarded as safe for the target animal, the dairy cow, when used as recommended. At the concentrations used for post milking sanitation (5000 ppm) their local and resorptive tolerance is good. In the rare case of a suspected or proven allergy of a herd, it is recommended to change to a non-iodine disinfectant.

4.7 Use during pregnancy, lactation or lay

This product can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For topical administration to the teats

Teat Dipping:

NCF Teat Dip is supplied ready to use as a teat dip. The teats should be dipped immediately after the cow has been milked. Each teat should be dipped at least 2cm into the disinfectant solution containing 5000ppm available Iodine immediately after each milking. Care should be taken to cover the whole teat.

Teat Spraying:

Ready-to-use. No dilution necessary. Each teat should be sprayed with disinfectant solution containing 5000ppm available iodine immediately after each milking. Care should be taken to cover the whole teat. Apply with applicators consisting of plastic or stainless steel components.

Udder Washing:

Dilute 75ml of NCF teat dip in 4 litres of water. Clean the udder with this solution before each milking. A fresh solution should be prepared daily.

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

Not applicable.

4.11 Withdrawal Period(s)

Meat and offal: Zero days

Milk: Zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiseptics and disinfectants, iodine.

ATCvet code: QD08AG03

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethoxylated long chain alcohol

Allantoin

Glycerine

Water

6.2 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: 3 years

6.4 Special precautions for storage

Do not store above 25°C. Protect from frost. Store in tightly closed original container.

6.5 Nature and composition of immediate packaging

5 and 20 litre HDPE containers with screw cap closures containing a clear dark brown fluid.

Not all pack sizes may be marketed.

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

Harmful to fish - do not contaminate ponds, waterways or ditches with chemical or used container.

Wash out container and dispose of safely.

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.

La Vallee House,

Upper Dargle Road,

Bray,

Co. Wicklow.

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10880/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT