

IRISH MEDICINES BOARD ACT 1995, as amended

European Communities (Animal Remedies) (No. 2) Regulations 2007

VPA: **10918/002/001**

Case No: 7008025

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:

Evans Vanodine International Plc

Brierley Road, Walton Summit, Preston PR5 8AH

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:

Masodine 1:3 Concentrate 2.15% w/v for Teat Dip/Spray Solution

The particulars of which are set out in the attached Schedule. The authorisation is also subject to any special conditions as may be specified in the Schedule.

The authorisation, unless 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: 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

Masodine 1:3 Concentrate 2.15% w/v for Teat Dip/Spray Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Iodine 2.15 % w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for teat dip/spray solution

Dark brown aqueous liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Dairy cows

4.2 Indications for use, specifying the target species

As an aid in the control of mastitis and as an aid in the prevention and healing of cracked and chapped teats in cows.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance.

4.4 Special warnings for each target species

Wash udders and teats before next milking.

If signs of disease persist or appear, consult your veterinary surgeon or veterinary practitioner.

Not to be applied to teats with broken or damaged skin.

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

Avoid contact with eyes. If splashed in the eyes, rinse with clean running water and seek medical advice.

In case of ingestion, seek medical attention immediately.

When used as a spray, avoid working in a spray mist.

Do not eat, drink or smoke whilst using the product.

Keep away from animal feed.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

For topical administration to the teats.

Teat Dipping

Prepare a solution of 1 part Masodine 1:3 with 3 parts water, to give 5000 ppm available iodine. Fill teat dipping cup about two thirds full with this solution and dip the teats immediately after each cow is milked. Top up the cup with fresh solution if necessary. Teat dip cups should be emptied and washed after every milking.

Teat Spraying

Prepare a solution of 1 part Masodine 1:3 to 3 parts water, immediately after milking spray the entire surface of each teat with the solution.

Udder Washing and Cluster Dipping

Dilute in the proportion 1:500 (i.e. 1 fl.oz. in 3 gallons). Immerse clusters and agitate for at least half a minute.

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

Not applicable.

4.11 Withdrawal Period(s)

Meat and offal: 0 days.

Milk: 0 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Dermatologicals, antiseptics and disinfectants, iodine.

ATC vet code: QD08AG03

5.1 Pharmacodynamic properties

Iodine has a powerful bactericidal action and is used for disinfecting unbroken skin before surgery. Iodine is also effective against fungi, viruses, protozoa, cysts and spores. It is generally employed as a 2% or 2.5% solution of iodine. The germicidal activity is reduced in the presence of organic matter although the reduction is reported to be less than that observed with other halogen disinfectants.

Iodophors (such as Masodine 1:3) as skin disinfectants have a wide range of activity against bacteria, fungi, viruses and some activity against bacterial spores; their action is rapid.

Iodophors do not stain and are non-irritant.

5.2 Pharmacokinetic properties

Iodine is slightly absorbed when applied to the skin. When taken by mouth, iodine preparations (which are converted to iodide) and iodides are trapped by the thyroid gland.

Iodides are excreted mainly in the urine, with smaller amounts appearing in the faeces, saliva and sweat. They cross the placenta and are excreted in milk.

Applications of povidone-iodine (iodophor) to large areas of broken skin should be avoided as excessive absorption of iodine may occur.

Studies involving 40 neonates indicated that topical application of povidone-iodine to the umbilical cord and surrounding area of normal intact skin resulted in significantly increased plasma-iodine concentrations.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

C₁₃/C₁₅ alcohol ethoxylate

Sorbitol (non-crystallising)

Glycerol

Sodium iodide

Potable water

6.2 Incompatibilities

1. Hypochlorite solutions and other oxidising agents.
2. Phenolic/soap/pine oil disinfectants.
3. Chlorhexidine teat disinfectants.
4. Alkaline soaps and detergents

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after dilution or reconstitution according to directions: 24 hours

6.4 Special precautions for storage

Store in tightly closed original container. Store below 25°C.

Store diluted product only in plastic or glass containers. Protect from frost.

Protect from light.

6.5 Nature and composition of immediate packaging

High density polyethylene 5 litre, 25 litre and 200 litre drums fitted with tamper-evident polypropylene cap.

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.

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

7 MARKETING AUTHORISATION HOLDER

Evans Vanodine International PLC,
Brierley Road,
Walton Summit,
Preston, PR5 8AH,
England.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10918/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT