IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

BLOCKADE 0.25 % w/w iodine teat dip solution

PRODUCT SUMMARY

EU Procedure Number	IE/V/0485/001 (formerly UK/V/0162/001)
Name, Strength, Pharmaceutical Form	BLOCKADE 0.25 % w/w iodine teat dip solution
Active Substances(s)	Iodine available (as iodine/poloxomer/sodium iodine/povidone complex)*
Applicant	DeLaval NV Industriepark-Drongen 10 B-9031 Gent Belgium
Legal Basis of Application	Application in accordance with Directive 2001/82/EC as amended.
Target Species	Cattle
Indication For Use	Teat disinfection as an aid in the prevention of mastitis.
ATC Code	QG52A
	28 January 2009
Date product first authorised in the Reference Member State (MRP only)	25 September 2001 (UK) 11 November 2002 (Ireland)
Concerned Member States for original procedure	Austria, Belgium, Czech Republic, Germany, Greece, Ireland (now RMS), The Netherlands UK added via RMS change

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.
The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

Blockade 0.25% w/w Iodine Teat Dip Solution is a topical application for use in cattle, and is used as a teat disinfectant aiding in the prevention of mastitis. Each teat is dipped immediately after milking into a teat cup containing the undiluted product. The dosage is 5 ml per animal per treatment.
The product is produced and controlled using validated methods and tests which ensure the consistency of the product released on the market. It has been shown that the product can be safely used in the target species, the slight reactions observed are indicated in the SPC[1]. The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.
This application was originally authorised under the National procedure in 2001, the Mutual Recognition procedure in 2003 and the Mutual Recognition Repeat Use Procedure in 2009.
[1] SPC – Summary of Product Characteristics.

II. QUALITY ASPECTS

A. Composition

The product contains available iodine 0.25% w/w, (2.5 mg/g, 12.8 mg per 5 ml dose), and the excipients citric acid monohydrate, glycerol, sodium iodate, sodium chloride, sodium hydroxide 29%, sorbitol solution 70%, xantham gum sodium iodide, poloxamer 335, povidone K30 and purified water.

The container/closure system consists of 5, 10, 20, 60 or 200 litre grey, high density polyethylene drums with screw closures and seals. The particulars of the containers and controls performed are provided and conform to the regulation.
The choice of the formulation was justified.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

Te active substance is iodine, an established active substance. The active substance is manufactured in accordance with the principles of good manufacturing practice. The active substance specification is considered adequate to control the quality of the

material. Batch analytical data demonstrating compliance with this specification have been provided.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

Suitable data were provided.

E. Control on intermediate products

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

F. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product. Satisfactory validation data for the analytical methods have been provided. Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

G. Stability

Stability data on the active substance has been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

H. Genetically Modified Organisms

Not applicable**.**

J. Other Information

Shelf-life:
Shelf-life of the veterinary medicinal product as packaged for sale: 1 year
Shelf-life after first opening the immediate packaging: 1 year

Special precautions for storage:

- Store upright and tightly closed in the original container
- Protect from frost
- If product has frozen, thaw in a warm room and shake well before using
- Protect from light
- Do not store above 30°C.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

The applicant conducted studies and provided bibliographical data. Iodine is thought to kill most bacteria, spores of *Bacillus* spp. and *Clostridium* spp. and viruses via an

oxidative-reductive reaction which involves the permanent transformation of carious cell wall constituents.

Toxicological Studies
Suitable toxicological data were supplied.

User Safety
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.
Warnings as cited in the approved SPC are considered satisfactory:-

- Care should be taken to reduce the possibility for eye contact. In case of eye contact, flush the eyes with copious amounts of water and seek medical advice.
- During application avoid contact with hands or wear protective gloves.
- Specific protection should be made for handling of the product from persons with iodine allergy (Gloves and gas mask).
- In case of ingestion, drink large quantities of water and obtain medical attention as soon as possible.

- Wash hands after use.

Ecotoxicity
The applicant provided a suitable environmental risk assessment in compliance with the relevant guideline which showed that no further assessment was required.
Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed:-

- Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
- The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

III.B Residues documentation
Suitable data were presented. The approved meat and milk withdrawal period for this product is zero days. Iodine and Iodophores have annex II entry in Regulation 2377/90 and maximum residues limits are therefore not required. The SPC carries the following direction with regard to withdrawal:-

Meat: Zero days.
Milk: Zero hours

Withdrawal Periods
Based on the data provided above, a withdrawal period of zero days for meat and zero days for milk are justified.

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies
Data on suitable studies were presented.

Pharmacology
Pharmacodynamics
Blockade is an antiseptic. The active form of this product is the free (molecular) iodine. Iodine solutions have a wide spectrum of activity against most bacteria species, spores of Bacillus and Clostridium and viruses. The mechanism of kill appears to be due to an oxidative-reductive reaction, involving carious cell wall constituents, which are irreversibly transformed. It appears sulfhydryl linkages, in bacteria cell wall components, are specifically targeted by the iodine.

Blockade is bactericidal (EN 1040 and EN 1656) against:
Pseudomonas aeruginosa
Staphylococcus aureus
Enterococcus hirae
Proteus vulgaris

Pharmacokinetics
The absorption of iodine through the intact skin is very low.

Tolerance in the Target Species of Animals
The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies
Laboratory Trials
The applicant reported suitable dose determination and confirmation studies.

Field Trials
Suitable studies were reported.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.