IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10277/053/001**
Case No: 7006162

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:

Schering Plough Limited

Shire Park, **Welwyn Garden City**, **Hertfordshire AL7 1TW**, **United Kingdom**

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:

Hibitex 0.425% w/v Teat Dip/Spray

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

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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

Hibitex 0.425% w/v Teat Dip/Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance		
Chlorhexidine digluconate	0.425	% w/v
(as Chlorhexidine Digluconate Solution)		
Excipients		
Benzalkonium Chloride	0.01	% w/v
Ponceau 4R (E124)	0.0021	% w/v

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Teat dip/spray solution.
A dark red solution.

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 in lactating dairy cows and in the prevention and healing of chapped teats.

4.3 Contraindications

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

4.4 Special warnings for each target species

Wash udder and teat before next milking.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

Hands must be washed after using Hibitex Teat Spray / Dip. Avoid working in the spray mist.
In cases of contact with eyes, give prolonged irrigation with water and obtain medical advice.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

To be used on lactating cows.

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.
Apply by dipping or spraying.

Teat Dipping: No dilution is required. Fill teat dipping cup about two thirds with Hibitex Teat Spray/Dip. Dip teats of every cow immediately after each cow is milked, ensuring that the full length of each teat is covered. Top up the cup with fresh solution as required. Teat dip cups should be emptied and washed after milking.

Teat Spraying: Immediately after milking spray the entire surface of each teat of every cow with Hibitex Teat Spray/Dip. No dilution is required.

Dosage: Applied undiluted for dipping or spraying cows' teats immediately after milking.

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

Not described.

4.11 Withdrawal Period(s)

Milk: 0 days. Milk may be taken for human consumption following treatment. Animals may be slaughtered for human consumption following treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antiseptics and disinfectants; Chlorhexidine.

ATCvet Code: QD08AC02.

5.1 Pharmacodynamic properties

Chlorhexidine is a bisbiguanide antiseptic and disinfectant which is bactericidal or bacteriostatic against a wide range of Gram positive and Gram-negative bacteria.

It is more effective against Gram-positive than Gram-negative bacteria, some species of *Pseudomonas* and *Proteus* being less susceptible. It inhibits mycobacteria. Chlorhexidine inhibits some viruses and is active against some fungi. It is inactive against bacterial spores at room temperature.

For pre-operative skin disinfection and hand washing, chlorhexidine is used as a 0.5 % solution of the acetate or gluconate in alcohol (70 %) or as a 4 % detergent solution of the gluconate.

For disinfection of wounds, burns, or other skin damage disorders, chlorhexidine is used as a 0.05 % aqueous solution of the gluconate.

For the emergency disinfection of clean instruments, a 2 minute immersion in chlorhexidine acetate or gluconate 0.5 % in alcohol (70 %) is used.

In obstetrics, chlorhexidine gluconate is used as a 0.05 % aqueous solution or a 1 % cream. The cream is also used as a barrier against bacterial hand infection.

5.2 Pharmacokinetic properties

Chlorhexidine is poorly absorbed from the gastro-intestinal tract and skin.

Chlorhexidine was detected in low concentrations in the venous blood of 5 to 24 infants after bathing with a preparation containing chlorhexidine gluconate 4%. No adverse effects due to percutaneous absorption of chlorhexidine were observed.

Low concentrations have been found in the venous blood of neonates following the topical use of a powder containing chlorhexidine 1%.

Percutaneous absorption of chlorhexidine was reported in pre-term neonates (but not full term infants) treated with chlorhexidine 1% in alcohol for neonatal cord care; no such absorption occurred when a dusting powder containing chlorhexidine 1% and zinc oxide was used.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Sorbitol (non-crystallising)
Isopropyl alcohol
Alcohol ethoxylate
Benzalkonium chloride
Ponceau 4R (E124)
Deionised water

6.2 Incompatibilities

Chlorhexidine digluconate is incompatible with soaps and other anionic materials and with suspending agents such as alginates and tragacanth. At concentrations of 0.05% chlorhexidine salts are incompatible with borates, bicarbonates, carbonates, chlorides, citrates, nitrates, phosphates and sulphates, forming salts of low solubility. Precipitates may form in hard water. Chlorhexidine is inactivated by cork.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

High density polypropylene 25 litre drum fitted with tamper-evident polypropylene cap.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.
Harmful to fish. Do not contaminate ponds, waterways and ditches with the licensed product or used container.

7 MARKETING AUTHORISATION HOLDER

Schering Plough Ltd.
Shire Park
Welwyn Garden City
Hertfordshire
AL7 1TW
England

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10277/053/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th september 2009

10 DATE OF REVISION OF THE TEXT