SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Luxspray 50V 0.5% w/v Teat dip / teat spray, solution — ready to use

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:
Iodine (available) 0.50 % w/v

Other relevant constituents:
Glycerol 10.3 % w/v
PEG 75 Lanolin 0.72% w/v
For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Teat dip / teat spray, solution
A non —viscous liquid with the brown colour and smell typical of iodine products.

4. CLINICAL PARTICULARS

The product is a bactericidal disinfectant containing iodine as the active agent. Iodine has a unique elemental bactericidal effect under acidic conditions.

4.1 Target species

Lactating dairy cows, sheep and goats

4.2 Indications for use, specifying the target species

When used as a teat dip / teat spray is an aid in the prevention of the spread of mastitis in lactating dairy cattle, sheep and goats.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Wash and dry udders and teats before next milking. Empty teat dipping beakers after each milking and wash before re-use.

4.5 Special precautions for use

i. Special precautions for use in animals

The product is a medicinal disinfectant for external use only.

ii. Special precautions for the person administering the veterinary medicinal product to animals

When used as a spray, avoid working in a spray mist.
Avoid contact with eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
If swallowed, seek medical advice immediately and show this container or label.
Hands and exposed skin should be washed after using this product.
Do not eat, drink or smoke while using the product.
Keep away from food, drink and animal feedstuffs.

iii. Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

No adverse reactions have been reported in similar iodine/iodophor based products.

4.7 Use during pregnancy, lactation or lay

Safe for use in pregnant and lactating cows, sheep and goats.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use in conjunction with any other treatment for disinfection of teats/udders — not compatible with chlorhexidine based teat dips. No other interactions known

4.9 Amount(s) to be administered and administration route

Ready to use preparation for the external application to the teats of lactating cows, sheep and goats.

Teat Dipping
Fill the dipping beakers two thirds (2/3) full and apply to the teats of the lactating cows, sheep or goats immediately after milking. The dipping beakers should be emptied after each milking and washed before reuse. Replenish dipping beakers after each milking.

Teat Spraying
Immediately after the milking of cows, sheep or goats spray the entire surface of each teat.

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

Not applicable — external teat surface treatment only.

4.11 Withdrawal period(s)

Meat & offal: Zero days and Milk: Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Products for teats and udder, Disinfectants

ATC Vet Code: QG52A

Iodine, formulated as an iodophor, is a halogen with an oxidising biocidal action against most mastitis pathogens.

5.1 Pharmacodynamic properties

The active ingredient is a disinfectant with bactericidal activity against most bacteria. The post milking topical application of the product to the teats of lactating cows, sheep and goats prevents the ingress of pathogenic organisms into the streak canal of the teat and thereby aids in the prevention of the spread of mastitis from infected quarters to non-infected quarters.

5.2 Pharmacokinetic properties

Although there is some evidence that iodine may be absorbed through teat skin, most iodine in milk is from dietary sources. Iodine has been determined in milk principally as the iodide. In the UK, the Committee on Toxicity of Chemicals in Food, Consumer Products concluded that the concentrations of iodine in cows' milk are unlikely to pose a risk to health after the determination of iodine levels in milk in 1998/9.
The Committee for Veterinary Medicinal Products (CVMP) has concluded that it would be inappropriate to elaborate Maximum Residue Limits (MRLs) for iodine and that iodine should therefore be included in Annex II of Council Regulation 2377/90/EEC (CVMP, 1996; Annex E).

6. PHARMACEUTICAL PARTICULARS

Luxspray 50V is a ready to use teat dip/spray containing iodine (as an iodophor) and emollients as an aid in the prevention of the spread of mastitis in lactating dairy cattle, sheep and goats.

6.1 List of excipients

Glycerol
Peg 75 Lanolin
Alcohol 6 mole ethoxylate

Alcohol 6 mole ethoxylate: 3 mole propoxylate co-polymer
Ethylene oxide: propylene oxide block copolymer
Water Potable

6.2 Incompatibilities

Iodine based teat dips are not compatible with chlorhexidine based products, hypochlorite solutions and other oxidising agents and alkaline soaps and detergents

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 1 year.

6.4 Special precautions for storage

Store below 20 °C.
Protect from frost.
Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

1. 25, 30 and 45 litre natural, high density polythene container with high density polyethylene cap (screw fit, tamper evident) with expanded polyethylene foam washer.
2. 200 litre blue high density polyethyene drum with polypropylene bung (tamper evident).
3. 1000 litre Intermediate Bulk Containers (IBCs) made of a polyethylene inner bottle contained within a metal cage mounted on metal or plastic pallet. Tamper evident seals to lids and outlets to be used.

Not all pack sizes may be marketed.

The 200 litre and 1000 litre container should not be returned for refilling.

For the 1000 litre Intermediate Bilk Container ensure that all equipment and containers used for the decanting of not more than enough product for use that day, are fit for purpose, clean, emptied after use and washed before re-use.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
To dispose of unused product to land you must have an authorisation under the Groundwater Regulations 2009.
Harmful to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

7. MARKETING AUTHORISATION HOLDER

GEA FARM TECHNOLOGIES (UK) LTD
Wylye Works
Watery Lane
Bishopstrow
Warminster
Wiltshire
BA12 9HT

8. MARKETING AUTHORISATION NUMBER

Vm 01808/4017

9. DATE OF FIRST AUTHORISATION

11 April 2008

10. DATE OF REVISION OF THE TEXT

July 2018

Approved 25 July 2018