

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hamra Blue, 0.40% w/w Teat Dip or Teat Spray Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Qualitative composition</u>	<u>Quantitative composition</u>
<u>Active substance</u> Chlorhexidine digluconate	0.41% w/v = 0.40% w/w (as chlorhexidine digluconate 20% w/v solution).
<u>Excipients</u> Contains Patent Blue V (E 131)	0.0002 % w/v.

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Teat dip / teat spray solution.
Clear blue liquid.

4. CLINICAL PARTICULARS

4.1. Target species

Lactating dairy cattle

4.2. Indications for use, specifying the target species

Teat disinfectant (dip or spray), prophylactic (as an aid in the prevention of mastitis in lactating dairy cattle).

4.3. Contraindications

None.

4.4. Special warnings for each target species

Wash and dry udder and teats before milking.
For external use only.
Teat dip cups should be emptied after milking and washed before re-use.
If signs of disease persist or appear, consult your veterinary surgeon.

4.5. Special precautions for use

- i) Special precautions for use in animals

None.

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

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.

In case of ingestion, drink large quantities of water and obtain medical attention as soon as possible.

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

Wash hands after use.

- iii) Other precautions

None.

4.6. Adverse reactions (frequency and seriousness)

None known.

4.7. Use during pregnancy, lactation or lay

For use during lactation.

4.8. Interaction with other medicinal products and other forms of interaction

Not to be used concurrently with soaps and anionic substances.

4.9. Amount to be administered and administration route

Use undiluted immediately after milking.

Fill cup three quarters full and dip each teat full length immediately after each milking, or spray entire surface of each teat after milking.

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

Not applicable.

4.11. Withdrawal period

Meat / milk: zero days / hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiseptics and disinfectants
ATCVet Code: QD08AC02

5.1. Pharmacodynamic properties

Hamra blue is an antiseptic. The active ingredient is chlorhexidine digluconate, which is a bisbiguanide antiseptic and disinfectant effective against a wide range of bacteria, some fungi and some viruses. Emollients are present to aid in protecting teats against sores and cracks.

5.2. Pharmacokinetic particulars

Not applicable (topical disinfectant).

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Patent Blue V (E131)
Glycerol
Sorbitol Liquid (Non-crystallising)
Isopropyl Alcohol
Alcohol 8 Mole ethoxylate
Simeticone
Citric acid monohydrate
Sodium hydroxide
Water Purified

6.2. Incompatibilities

None known.

6.3. Shelf life

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

6.4. Special precautions for storage

Store upright in tightly closed original container.
Do not store above 25°C.
Store in a dry place.
Protect from direct sunlight.
Do not freeze.
Store away from food, drink & animal feedstuffs.
Do not mix with other chemicals.
Used cans should not be recycled.

6.5. Nature and composition of immediate packaging

20 litre and 200 litre pigmented high density polyethylene drums with high density polyethylene screw-fit caps.

Screw-caps: Blue (20L)
 White (200L)
Seals: Blue (20L)
 Red (200L)

Not all pack sizes may be marketed.

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.

Do not contaminate ponds, waterways or ditches with product or empty container.

7. MARKETING AUTHORISATION HOLDER

DeLaval NV
Industriepark-Drongen 10
B-9031 Gent
Belgium

8. MARKETING AUTHORISATION NUMBER


Vm: 17140/4005

9. DATE OF FIRST AUTHORISATION

Date: 13 July 1992

10. DATE OF REVISION OF THE TEXT

Date: May 2014

 03 June 2014