

KENOSTART SPRAY AND DIP
3 mg/g Teat Dip or Spray Solution for cattle (dairy)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

CIDLINES NV
Waterpoortstraat 2
8900 Ieper
Belgium
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2. NAME OF THE VETERINARY MEDICINAL PRODUCT
KENOSTART SPRAY AND DIP 3 mg/g Teat Dip or Spray Solution for cattle (dairy)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT
Available Iodine, 3 mg/g

4. INDICATION
Teat disinfection as part of a prevention strategy for mastitis in cattle.

5. CONTRAINDICATIONS
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS
Inform your veterinary surgeon if adverse reactions occur using the veterinary medicinal product.
Repeated exposure to iodine can lead to iodine allergy. Allergic reactions to iodine may become apparent as allergic skin reaction but also as anaphylactic shock in rare cases.

7. TARGET SPECIES
Cattle (dairy).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
The product is suitable for dipping or spraying immediately after each milking. The veterinary medicinal product is supplied ready to use a teat dip or spray. If a dip cup is used, it should hold at least 5ml of veterinary medicinal product. Dip the teats immediately after milking each cow. Ensure that the teat is completely covered to three quarters of its length.

For the teat spraying, spray the entire surface of each teat with the veterinary medicinal product immediately after milking. The dip cup or sprayer should be replenished as necessary. The dip cup or sprayer should be emptied after milking and washed before reused. The product is meant to be used as a post-milking teat dip or spray up to two times per day.

9. WITHDRAWAL PERIOD

Meat & offal: zero days

Milk: zero days

10. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of the children

Store in the original container

Keep the container tightly closed

Protect from frost

If the veterinary medicinal product has frozen, thaw in a warm place and shake well before use

Protect from light

Do not use after the expiry date stated on the label

Shelf life after first opening the immediate packaging: 6 months

11. SPECIAL WARNING(S)

Ensure udder and teats are clean and dry before the next milking.

Can be used during pregnancy and lactation.

In absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

This veterinary medicinal product is for topical application, significant absorption does not occur.

Special precautions for use in animals

- For animal treatment only
- For external use only
- Use for the treatment of teats with cutaneous lesions may delay wound-healing. It is recommended to discontinue the treatment until lesions are healed.

Operator Warnings

- Avoid contact with eyes. If splashed in the eye, rinse with clean running water and seek medical advice.
- In case of ingestion, drink large quantities of water and seek medical attention immediately.
- Keep away from food and animal feed.
- Wash hands after use.
- When used as a spray, avoid working in the spray mist. Those who are hypersensitive to iodine should avoid using this product.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

UK only: To dispose of unused product to land, you must have an authorization under the Groundwater Regulations 1998.

13. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

14. OTHER INFORMATION

PHARMACEUTICAL FORM

Teat Dip or Spray Solution
Dark brown liquid solution

ROUTE OF ADMINISTRATION

Teat use

PACKAGE SIZES

1L, 5L, 10L, 20L, 25L, 60L, 200L. Not all pack sizes may be marketed.

EXPIRY DATE

EXP: MM/YYYY*

* The format used for the expiry date is Month/Year for example 10/2008.

BATH NUMBER

EXP: AA/BB/CC**

** The format used for the bath number is Year/Week/Number starting by 50 (rising number)

For example the first batch produced in 2007 in week 1 has the batch number: 700150

MARKETING AUTHORISATION NUMBER

UKonly:

Marketing Authorisation Number: Vm22136/4001

Transport Emergency: For UK transport emergencies only phone 01865407333

AMV-GSL

IE only:

Marketing Authorisation Number: VPA 10792/2/1

LM (Licensed Merchant)

Discard date: _____