

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX 1 x 60 ml
BOX 6 x 60 ml
BOX 12 x 60 ml
BOX 24 x 60 ml
BOX 48 x 60 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Locatim oral solution for neonatal calves less than 12 hours of age

2. STATEMENT OF ACTIVE SUBSTANCES

Bovine concentrated lactoserum containing specific immunoglobulins G against *E. coli* F5 (K99) adhesin $\geq 2.8 \log_{10}/\text{ml}$.

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

60 ml.
6 x 60 ml
12 x 60 ml
24 x 60 ml
48 x 60 ml

5. TARGET SPECIES

Neonatal calves less than 12 hours of age.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 °C – 8 °C).
Keep the bottle in the outer carton.
Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory, see package leaflet for further information.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Biokema Europe
Centre des Affaires des Lilas
77 Avenue des Lilas
64000 Pau
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 57846/5000

17. MANUFACTURER'S BATCH NUMBER

Batch{number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

INTERNAL TECHNICAL BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Locatim oral solution for neonatal calves less than 12 hours of age

2. STATEMENT OF ACTIVE SUBSTANCES

Bovine concentrated lactoserum containing specific immunoglobulins G against *E. coli* F5 (K99) adhesin $\geq 2.8 \log_{10}/\text{ml}$.

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

6 x 60 ml.

5. TARGET SPECIES

Neonatal calves less than 12 hours of age.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 °C – 8 °C).
Keep the bottle in the outer carton.
Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory, see package leaflet for further information.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Biokema Europe
Centre des Affaires des Lilas
77 Avenue des Lilas
64000 Pau
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 57846/5000

17. MANUFACTURER’S BATCH NUMBER

Batch{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Locatim oral solution for neonatal calves less than 12 hours of age

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Bovine concentrated lactoserum containing specific immunoglobulin G against *E. coli* F5(K99) adhesin $\geq 2.8 \log_{10}/\text{ml}$

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

60 ml

4. ROUTE(S) OF ADMINISTRATION

Oral administration of 60 ml as soon as possible, preferably given within the first 4 hours, but not later than 12 hours after birth.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Locatim oral solution for neonatal calves less than 12 hours of age

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

Marketing authorisation holder and manufacturer responsible for batch release:

Biokema Europe
Centre des Affaires des Lilas
77 Avenue des Lilas
64000 Pau
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Locatim oral solution for neonatal calves less than 12 hours of age

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Bovine concentrated lactoserum containing specific immunoglobulins G against *E. coli* F5 (K99) adhesin $\geq 2.8^* \log_{10}/\text{ml}$.

* ELISA method

Methyl parahydroxybenzoate $\leq 0.8 \text{ mg/ml}$.

4. INDICATION(S)

Reduction of mortality caused by enterotoxigenic associated with *E. coli* F5 (K99) adhesin during the first days of life as a supplement to colostrum from the dam.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None known.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Neonatal calves less than 12 hours of age.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral administration of 60 ml as soon as possible, preferably given within the first 4 hours, but not later than 12 hours after birth.

9. ADVICE ON CORRECT ADMINISTRATION

The product should be administered neat or diluted in milk or in milk replacer within the first 12 hours of the calf's life, preferably, as soon as it is receptive. If the calf is reluctant to take the product, it may be administered via an ordinary syringe placed in the mouth.

The calf must be given other normal colostrum in addition to the product.

In the absence of information specifically demonstrating the safety of more than one repeated dose, it is recommended that calves should only be dosed once.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).

Keep the bottle in the outer carton.

Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNINGS

Special warnings for each target species:

The product is produced from colostrum collected from cows kept under field conditions. Consequently, in addition to antibodies to *E. coli* F5 (K99) it also contains antibodies to other organisms, as a result of vaccination and/or exposure of the donor cows to organisms in their environment. This should be borne in mind when planning vaccination programmes for calves, which receive Locatim.

Special precautions for use in animals:

This product may contain antibodies against BVD virus.

Pregnancy and lactation:

The product is not intended for use during pregnancy and lactation.

Interactions with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy of this product when used with any other veterinary medicinal product. A decision to use this product before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes):

Transient effects of temperature increase and respiration rate increase have been seen when the product is administered in a double dose.

Incompatibilities:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2023

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu>).

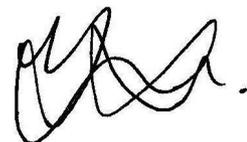
15. OTHER INFORMATION

The product supplements the protective properties of normal colostrum against *E. coli* F5 (K99) adhesin.

Pack size: 1, 6, 12, 24 or 48 60 ml bottles.

The manufacture, import, possession, sale, supply and/or use of Locatim may be prohibited in a Member State on the whole or part of their territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and use Locatim must consult the relevant Member State's competent authority on the current animal health policies prior to the manufacture, import, possession, sale, supply and/or use.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.



Approved: 10 May 2023