1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

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

Excipient

Methyl parahydroxybenzoate ≤ 0.8 mg/ml.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution

4. CLINICAL PARTICULARS

4.1 Target species

Neonatal calves less than 12 hours of age.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

None.

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals

This product may contain antibodies against BVD virus.

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

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy or lactation

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

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

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

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

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

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

The product supplements the protective properties of normal colostrum against *E. coli* F5 (K99) adhesin.
ATCvet code: QI02AT01.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Cardboard box with 1, 6, 12, 24 or 48 60 ml type III glass bottles closed with a polypropylene stopper with a polyethylene seal and a detachable lock-ring.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Biokema Anstalt,
Pflugstrasse 12,
9490 Vaduz,
Fürstentum
LIECHTENSTEIN

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/99/011/001
EU/2/99/011/002
EU/2/99/011/003
EU/2/99/011/004
EU/2/99/011/005

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29/03/1999.
Date of last renewal: 05/12/2008.

10. DATE OF REVISION OF THE TEXT

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

PROHIBITION OF SALE, SUPPLY AND/OR USE

The manufacture, import, possession, sale, supply and/or use of Locatim may be prohibited in a Member State on the whole or part of its 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 vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.