ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

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

<u>Special precautions for use in animals</u>

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.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

<u>Name and address of the manufacturer of the biological active substance</u>

Biokema SA
Chemin de la Chatanérie 2
1023 Crissier-Lausanne
SWITZERLAND

<u>Name and address of the manufacturer responsible for batch release</u>

Biokema Anstalt,
Pflugstrasse 12,
9490 Vaduz,
FÜRSTENTUM LIECHTENSTEIN

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce passive immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients listed in section 6.1 of the SPC are allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required.

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 ≥2.8 log_{10}/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 Anstalt,
Pflugstrasse 12,
9490 Vaduz,
Fürstentum
LIECHTENSTEIN

16. 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

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 ≥2.8 $\log_{10}$/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 Anstalt,
Pflugstrasse 12,
9490 Vaduz,
Fürstentum
LIECHTENSTEIN

16. 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

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 $\geq 2.8 \log_{10}$/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 Anstalt,
Pflugstrasse 12,
9490 Vaduz,
FÜRSTENTUM LIECHTENSTEIN

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 ≥2.8* $\log_{10}$/ml.
* ELISA method

Methyl parahydroxybenzoate ≤ 0.8 mg/ml.

4. INDICATION(S)

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.

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

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.