

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Locatim oral solution

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

### **Active substance(s)**

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

\* microagglutination method

### **Excipients**

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

Propyl parahydroxybenzoate  $\leq 0.2 \text{ mg/ml}$

## **3. PHARMACEUTICAL FORM**

Oral solution

## **4. IMMUNOLOGICAL PROPERTIES**

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

ATC vet code: QI02AT01

## **5. CLINICAL PARTICULARS**

### **5.1 Target species**

Neonatal calves less than 12 hours of age

### **5.2 Indications for use**

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

### **5.3 Contraindications**

None

### **5.4 Undesirable effects (frequency and seriousness)**

None known

### **5.5 Special precaution for use**

This product may contain antibodies against BVD virus.

## **5.6 Use during pregnancy and lactation**

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

## **5.7 Interaction with other vaccines and medicinal products when administered in combination with the product**

No information is available on the safety and efficacy from the concurrent use of this product with any other immunological product.

## **5.8 Posology 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.

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.

## **5.9 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.

## **5.10 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.

## **5.11 Withdrawal period**

Zero days

## **5.12 Special precautions to be taken by the person administering the medicinal product to animals**

None

# **6. PHARMACEUTICAL PARTICULARS**

## **6.1 Major incompatibilities**

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

## **6.2 Shelf life**

30 months

### **6.3 Special precautions for storage**

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

### **6.4 Nature and contents of container**

Cardboard box with one 60 ml type III glass bottle closed with a polypropylene stopper with a polyethylene seal and a detachable lock-ring.

### **6.5 Special precautions for the disposal of unused product or waste materials , if any**

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

## **7. NAME OR CORPORATE NAME AND ADDRESS OR REGISTERED PLACE OF BUSINESS OF THE MARKETING AUTHORISATION HOLDER**

Biokema Anstalt,  
Aeulestrasse 38,  
9490 Vaduz,  
Fürstentum Liechtenstein

### **Prohibition of sale, supply and/or use**

The import, sale, supply and/or use of the product is/or may be prohibited in certain Member States on the whole or part of their territory pursuant to National animal health policy. Any person intending to import, sell, supply and/or use the product has to consult the relevant Member States' Competent Authorities on the current animal health policies prior to the import, sale, supply and/or use.

### **Marketing Authorisation number**

EU/2/99/011/001

### **Date of first authorisation/renewal of the authorisation**

28.04.2004

### **Date of revision of the text**

28.04.2004