

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanoprim Bolus

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each bolus contains :

##### Active substances

Trimethoprim	200.0 mg
Sulphadiazine	1.0 g

For a full list of excipients see section 6.1.

#### 3 PHARMACEUTICAL FORM

Tablet

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

Calves and horses

##### 4.2 Indications for use, specifying the target species

A broad spectrum anti-bacterial indicated for the treatment of gastrointestinal infections due to a wide range of gram positive and gram negative organisms.

##### 4.3 Contraindications

Do not use for the treatment of systemic infections in animals with functional rumens.  
Do not use in animals with known hypersensitivity to the active ingredients.  
Do not administer to foals less than 4 days old.

##### 4.4 Special warnings for each target species

None known

##### 4.5 Special precautions for use

###### Special precaution(s) for use in animals

None.

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

None.

#### **4.6 Adverse reactions (frequency and seriousness)**

None known.

#### **4.7 Use during pregnancy, lactation or lay**

Not applicable.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.9 Amounts to be administered and administration route**

The bolus may be dispersed in water and administered as a drench or administered directly by hand or via balling gun. The recommended dosage rate is one bolus per 40 kg bodyweight daily (equivalent to 30 mg of combined active per kg bodyweight). It should be divided and given twice daily. Continue treatment until two days after clinical signs have disappeared up to a maximum of 5 days. Where salmonellosis is present it is necessary to continue the treatment for five consecutive days.

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

Not applicable.

#### **4.11 Withdrawal Period(s)**

Animals must not be slaughtered for human consumption during treatment. Cattle intended for human consumption may be slaughtered only after 21 days from the last treatment. Horses intended for human consumption may be slaughtered only after 6 months from the last treatment.

Milk: not applicable.

### **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Chanoprim bolus is a broad spectrum anti-bacterial, active against a wide range of Gram-positive and Gram-negative organisms. The two active ingredients trimethoprim and sulphadiazine both sequentially block bacterial and protozoal synthesis of folinic acid thus giving a level of activity many times greater than that obtained from either drug alone.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Maize Starch  
Lactose  
Povidone K30  
Magnesium Stearate  
Sodium Starch Glycollate Type A

#### **6.2 Incompatibilities**

None known.

### **6.3 Shelf-life**

2 years.

### **6.4 Special precautions for storage**

Store below 25°C.  
Protect from light.

### **6.5 Nature and composition of immediate packaging**

**50's:** Crystal polystyrene container with polypropylene lids and alu-thermo seals.

**100's:** Polypropylene containers with high density polyethylene tamper evident lids.

### **6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials**

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

## **7 MARKETING AUTHORISATION HOLDER**

Chanelle Pharmaceuticals Manufacturing Ltd.,  
Loughrea,  
Co. Galway.

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10987/6/1

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

1<sup>st</sup> October 2003