

## Summary of Product Characteristics

### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Protect Oral Suspension for New Born Calves.

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Lactobacillus acidophilus strain LA-101

Lactobacillus acidophilus strain LA-107

Enterococcus faecium strain SF-101

Minimum content of each strain is more than  $1.0 \times 10^8$  cfu/ml at time of use.

Excipients:

Butyl hydroxyanisole (E320) 0.00096 % w/w

Butyl hydroxytoluene (E321) 0.00107 % w/w

DL-alpha-tocopherol (E307) 0.008 % w/w

For the full list of excipients see section 6.1

### 3 PHARMACEUTICAL FORM

Oral Suspension.

Light brown viscous suspension for oral administration.

### 4 CLINICAL PARTICULARS

#### 4.1 Target Species

Calves in their pre-ruminant phase, up to the age of 12 weeks.

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

For use as an aid in the prevention of bacterial diarrhoea in young calves, up to the age of 12 weeks.

#### 4.3 Contraindications

Do not use while administering therapeutic or in feed antibiotics.

#### 4.4 Special warnings for each target species

None.

#### **4.5 Special precautions for use**

i) Special precautions for use in animals

None.

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

Wash hands after use.

Avoid contact with eyes.

If eye contact occurs, rinse eye with clean, fresh water immediately.

If irritation occurs seek medical advice.

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

None reported.

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

Not relevant. Only for use in pre-ruminant calves.

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

Chlortetracycline, oxytetracycline, tetracycline, penicillin, virginiamycin and tylosin have all been shown to be antagonistic to lactic acid bacteria.

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

Shake the bottle before use.

Prime the automatic dose dispenser by inverting the bottle after attachment and gently squeezing the pump.

Shake the container before administering each dose.

Do not mix the contents or rinse the dispenser with water.

A dose of 5 ml (2 doses from applicator) per calf should be administered orally:

- As soon as possible after birth
- To bought-in calves on arrival at the farm
- At times of stress, as necessary.

For the following two days, 2.5 ml/head (1 dose) should be administered before the morning feed.

One dose is administered by each stroke of the pump through the short dispensing nozzle of the dose dispenser into the calf's mouth.

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

None.

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

Meat and offal: Zero days.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

**Pharmacotherapeutic group:** Antidiarrhoeal microorganisms, lactic acid producing organisms, combinations.

**ATC Vet code:** QA07FA51.

The product contains a combination of three bacterial strains:

Lactobacillus acidophilus strain LA-101

Lactobacillus acidophilus strain LA-107

Enterococcus faecium strain SF-101

These probiotics have been demonstrated to benefit the host animal by positively influencing the intestinal flora.

The three strains of lactic acid forming bacteria used in the product have all been shown, *in vitro*, to be inhibitory to 8 pathogens common to farm animals. The pathogens tested were: *E.coli* strains K88 and K99, *Salmonella typhimurium*, *dublin* and *enteritidis*; *Staphylococcus aureus*, *Clostridium perfringens* and *Listeria monocytogenes*.

The organisms may produce a beneficial effect on an animal by influencing microbial metabolism in the gut or suppressing levels of harmful bacteria. Mechanisms of action of probiotic cultures to reduce levels of pathogens have been proposed. These include production of inhibitory substances and increased competition for adhesion sites in the alimentary tract.

### 5.1 Pharmacodynamic properties

Not yet defined.

### 5.2 Pharmacokinetic properties

Not yet defined.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Butylhydroxyanisole (E320) in vegetable oil  
Butylhydroxytoluene (E321) in vegetable oil  
DL alpha-tocopherol  
Sunflower Oil  
Silica colloidal anhydrous (Aerosil 380)  
Orange Oil (Sweet)  
Polysorbate 80  
Ethyl Maltol  
Dried yeast

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf-life**

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.  
Shelf life after first opening the immediate packaging: 3 months.

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

Store between 2-8°C  
Protect from light.  
Do not freeze.  
Discard unused material.

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

White, opaque, high density polyethylene (HDPE) 100ml bottle with a white opaque, screw fit HDPE cap. Contents administered via a HDPE metered dose pump contained within the cap, delivering 2.5ml.

Available in cartons of 1 x 100 ml.

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

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**

Provita Eurotech Limited,  
21 Bankmore Road,  
Omagh BT79 OEU,  
Co. Tyrone,  
Northern Ireland.

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

VPA 10865/001/001

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

30<sup>th</sup> October 2003

**10 DATE OF REVISION OF THE TEXT**

August 2014