## 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

**Excipients:**
Sunflower Oil
Silica colloidal anhydrous (Aerosil 380)
Orange Oil (Sweet)
Polysorbate 80
Dried Yeast

## 3. CLINICAL INFORMATION

### 3.1 Target species

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

### 3.2 Indications for use for each target species

For use as an aid in the prevention of bacterial diarrhoea in young calves, up to the age of 12 weeks. Probiotics have been demonstrated to benefit the host animal by positively influencing the intestinal flora

### 3.3 Contraindications

Do not use while administrating therapeutic or in-feed antibiotics.

### 3.4 Special warnings

None.

### 3.5 Special precautions for use

Special precautions for use in the target species;

None.

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.

Special precautions for the protection of the environment:

None.

Other precautions:

None.

### 3.6 Adverse events

None have been observed.

### 3.7 Use during pregnancy, lactation or lay

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

### 3.8 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.

### 3.9 Administration routes and dosage

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 5ml (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, 2.5ml / 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.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Meat and offal: Zero days

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet 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.

### 4.2 Pharmacodynamics

Not yet defined.

### 4.3 Pharmacokinetics

Not yet defined.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

None known.

### 5.2 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.

### 5.3 Special precautions for storage

Keep out of the sight and reach of children.
Store in a refrigerator (2ºC - 8º C)
Protect from light.
Do not freeze.
Discard unused material.
Keep bottle in outer carton

### 5.4 Nature and composition of immediate packaging

White, opaque, high density polyethylene (HDPE) 100ml bottle with a white opaque, screw fit HDPE cap. Contents administrated via a HDPE metered dose pump supplied with each bottle, each pump delivering 2.5ml.

Available in cartons of 1 x 100ml

### 5.5 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.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Provita Eurotech Ireland Limited

**MANUFACTURER RESPONSIBLE FOR BATCH RELEASE FOR IE and UK:**

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## 7. MARKETING AUTHORISATION NUMBER(S)

VPA23471/001/001

## 8. DATE OF FIRST AUTHORISATION

30/10/1998

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

16/06/2026

**LIMITED MARKETS:**

Not Applicable.

**EXCEPTIONAL CIRCUMSTANCES:**

Not applicable.

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

| IE only | UK only |
|---|---|
| LM | POM-VPS |
| Licensed Merchant | May be prescribed by any Registered Qualified Person (RQP) – a veterinarian, a pharmacist or an appropriately qualified SQP |

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).