

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 1.0×10^8 cfu/ml at time of use.

Excipients:

Butyl hydroxyanisole (E320)	0.00096% w/w
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Butyl hydroxytoluene (E321)	0.00107% w/w
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DL-alpha-tocopherol (E307)	0.008% w/w
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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 the 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 Amount(s) 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 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.

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

None.

4.11 Withdrawal period

Meat and offal: Zero days

5. PHARMACOLOGICAL 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 in a refrigerator (2°C-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 product or waste materials derived from the use of such products, if appropriate

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 AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Provita Eurotech Limited, 21 Bankmore Road, Omagh, Co.Tyrone, BT79 0EU, Northern Ireland.

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8. MARKETING AUTHORISATION NUMBERS

IE only	UK only
VPA: 10865/001/001	VM: 11543/4001
LM	POM-VPS
Licensed Merchant	To be supplied only on veterinary prescription

9. DATE OF FIRST AUTHORISATION

Date: 20 December 1995

10. DATE OF REVISION OF THE TEXT

June 2014

 26 June 2014