

**PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGE**  
**{NATURE/TYPE}**

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

Protect Oral Suspension for New Born Calves

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

**Active ingredients:** A stable suspension of Lactobacillus acidophilus strains LA-101 and LA-107, and Enterococcus faecium strain SF-101. Minimum content of each strain > 1.0 x 10<sup>8</sup> cfu/ml at time of use.

**3. PHARMACEUTICAL FORM**

Oral suspension

**4. PACKAGE SIZE**

**5. TARGET SPECIES**

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

**6. INDICATION(S)**

As an aid in the prevention of bacterial diarrhoea in young calves, up to the age of 12 weeks. Protect can be used at birth, for bought in calves on arrival at the farm and at times of stress, as necessary.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Attach pump to bottle, prime the automatic dose dispenser by inverting the bottle after attachment and gently squeezing the pump, shake container well before administering each dose. 2 strokes of pump (5.0ml) administered orally:

- as soon as possible after birth
- to bought-in calves on arrival at farm
- at times of stress, as necessary

Then 1 stroke of pump (2.5ml) before morning feed on the following two days. One dose is administered by each stroke of the pump through the short dispensing nozzle of the dose dispenser into the calf's mouth.

**8. WITHDRAWAL PERIOD**

Meat and offal – Zero days

## **9. SPECIAL WARNING(S), IF NECESSARY**

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. Read package leaflet before use.

## **10. EXPIRY DATE**

## **11. SPECIAL STORAGE CONDITIONS**

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

Following first use, use the product within 3 months. Discard unused materials.

## **12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

## **13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]**

POM- VPS
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For animal treatment only. To be supplied only on veterinary prescription

## **14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

## **15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

**Provita Eurotech Limited**

21 Bankmore Road, Omagh Co. Tyrone,

Northern Ireland BT79 0EU

## **16. MARKETING AUTHORISATION NUMBER(S)**

**Vm 11543/4001**

## **17. MANUFACTURER’S BATCH NUMBER**

**PACKAGE LEAFLET FOR:**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

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

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Protect Oral Suspension for New Born Calves

**3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS**

A stable suspension of *Lactobacillus acidophilus* strains LA-101 and LA-107, and *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.

An oral suspension.

Light brown viscous suspension for oral administration.

**4. INDICATION(S)**

Protect for New Born Calves (up to the age of 12 weeks) should be used at birth, for bought-in calves on arrival at farm or

at times of stress, as an aid in the prevention of bacterial diarrhoea. Probiotics have been demonstrated to benefit the host animal by positively influencing the intestinal flora.

**5. CONTRAINDICATIONS**

Do not use whilst administering therapeutic or in feed antibiotics.

**6. ADVERSE REACTIONS**

None reported.

**7. TARGET SPECIES**

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

For Animal Treatment Only.

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

Use in prevention of bacterial diarrhoea in young pre-ruminant calves to 12 weeks of age. 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 contents or rinse 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 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. When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

## **9. ADVICE ON CORRECT ADMINISTRATION**

### **10. WITHDRAWAL PERIOD(S)**

Meat and offal: Zero days

### **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Store in a refrigerator (2°C -8°C).

Protect from light.

Do not freeze.

Shelf life after first opening the container: use the product within 3 months. Discard unused materials.

Keep container in outer carton

When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

### **12. SPECIAL WARNING(S)**

## User warnings

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.

## Pregnancy, lactation or lay

Not relevant. For use in pre-ruminant calves.

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

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

For Animal Treatment Only

## 13. 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.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

## 15. OTHER INFORMATION

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*Vm 11543/4001*

Mechanisms have been proposed for the benefits derived from use of probiotic bacteria in young calves. These include production of inhibitory substances and increased competition for adhesion sites in the alimentary tract wall. The three strains of lactic acid bacteria used in **Protect** have been shown, in vitro, to inhibit growth of eight pathogens common to farm animals, including *E. coli* strains, - K88 and K99; *Salmonella typhimurium*, *dublin* and *enteritidis*, *Staphylococcus aureus*, *perfringens* and *Listeria monocytogenes*.

## PACK SIZE

100 ml plastic bottle with 2.5 ml inverted pump delivery applicator for calves.

Approved: 08/01/2018

