

**MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}**

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

Marketing authorisation holder:

Alfasan Nederland B.V.  
Kuipersweg 9  
3449 JA Woerden  
The Netherlands

Manufacturer responsible for batch release:

Dales Pharmaceuticals Ltd  
Snaygill Industrial Estate  
Keighley Road  
Skipton  
North Yorkshire  
BD23 2RW  
United Kingdom

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

Birp oral emulsion for cattle

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

Contains:

Simethicone 1.0% w/v

Excipients :

Sodium propyl hydroxybenzoate  
Sodium methyl hydroxybenzoate

All white emulsion consisting of Emulsion of Simethicone.

**4. PHARMACEUTICAL FORM**

Oral emulsion.

**5. PACKAGE SIZE**

100 ml

**6. INDICATION**

For the relief of gaseous and frothy bloat in cattle.

For the treatment of gaseous and frothy bloat in cattle.

## **7. CONTRAINDICATIONS**

None known.

## **8. ADVERSE REACTIONS**

Secondary or free-gas bloat most often occurs in single animals, in which there is an obstruction or eructation. In such cases, treatment should be supported by diagnosis of the cause if the failure of eructation.

In outbreaks of primary frothy bloat, management strategies should be introduced to reduce foam production in the rumen or to control access of cattle to pasture or grains that promote excess gaseous foams.

## **9. TARGET SPECIES**

Cattle.

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

50 to 100 ml orally.

A further dose may be given 3 hours later if required.

## **11. ADVICE ON CORRECT ADMINISTRATION**

Cattle: The contents of one bottle as a drench. Shake the bottle before use. If signs of disease persist or appear, consult a veterinary surgeon.

## **12. WITHDRAWAL PERIOD**

Meat: Zero days; Milk: Zero hours

## **13. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Do not store above 25°C.

Do not freeze.

Use once then discard container and contents remaining after use.

## **14. SPECIAL WARNINGS**

User warnings:

Wash hands after use.

Use during pregnancy or lactation:

No special precautions.

## **15. EXPIRY DATE**

EXP: month/year

## **16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS**

Rinse container thoroughly with water.  
Dispose of rinsing's in slurry or dirty water.  
Dispose of rinsed containers in the farm refuse.  
Used container should not be recycled.

## **17. DATE ON WHICH THE LABEL WAS LAST APPROVED**

XX/XX/XX

## **18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only.

AVM-GSL

Authorised Veterinary Medicine – General Sales List

## **19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"**

Keep out of the sight and reach of children.

## **20. MARKETING AUTHORISATION NUMBER**

Vm 36408/4016

## **21. MANUFACTURER'S BATCH NUMBER**

Lot: {number}

## **22. OTHER INFORMATION**

UK authorised veterinary medicinal product.

100 ml bottle fitted with a drenching nozzle

Birp is a product containing a single active ingredient, simethicone, which is effective in reducing surface tension, particularly of semi-fluids and fluids. Its use therefore, in cases of frothy bloat, is specific. Whilst the normal route of administration is orally as a drench, it may be given directly into the rumen through a cannula, and in fact is often beneficial to combine both routes, if a cannula has been inserted.

As simethicone is relatively non-toxic, overdosage is unlikely, and repeated doses are advised in cattle.

Whilst most frothy bloat is treated parenterally, using an antihistamine, and surgically, using a trocar and cannula, cases are usually of an acute or even peracute nature, and require immediate relief. Unfortunately, frothy bloat is not like a simple bloat where there is only one large pocket of gas, which can be removed immediately on insertion of a cannula. Frothy bloat may be reduced by the use of a cannula, but empirical therapy is essential, otherwise the disorder will return or not even respond.

Local representative:

Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom.

Approved 18 August 2021

A handwritten signature in black ink, appearing to read "A. Hunter.", is positioned below the approval date.