

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{cardboard box with 1 vial of 1,000 or 5,000 doses;
cardboard box with 10 vials of 1,000 or 5,000 doses}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN GUMBORO Lyophilisate for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES**Each dose contains**

Avian infectious bursal disease (IBD) virus, live attenuated, intermediate IBDV_IGS strain, 3.0 -4.5 log₁₀ EID₅₀

3. PACKAGE SIZE

1 x 1,000 doses

1 x 5,000 doses

10 x 1,000 doses

10 x 5,000 doses

4. TARGET SPECIES

Chickens.

5. INDICATIONS**6. ROUTES OF ADMINISTRATION**

Oral use.

To be administered in the drinking water after resuspension.

7. WITHDRAWAL PERIOD(S)

Zero days.

8. EXPIRY DATE

Exp {mm/yyyy}

Once reconstituted: 2 hours

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2°C – 8°C).

Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS CALIER, S.A.

14. MARKETING AUTHORISATION NUMBER(S)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {1,000 or 5,000 doses}
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1. NAME OF THE VETERINARY MEDICINAL PRODUCT
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PRIMUN GUMBORO

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose contains

Avian infectious bursal disease (IBD) virus, live attenuated, intermediate IBDV_IGS strain, 3.0-4.5 log₁₀ EID₅₀

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp (mm/yyyy)

Once reconstituted: 2 hours