

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

{1x 1,000 doses}
{10x 1,000 doses}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN GUMBORO W2512 Lyophilisate for use in drinking water for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains:

Live attenuated avian infectious bursal disease (IBD) virus, intermediate plus IBDV_2512 strain
1.5 - 3.0 log₁₀ EID₅₀*

* EID₅₀ (embryo infectious dose 50%)

3. PHARMACEUTICAL FORM

Lyophilisate for use in drinking water

4. PACKAGE SIZE

1 x 1,000 doses

10 x 1,000 doses

5. TARGET SPECIES

Chickens (broiler)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage: 1 dose /animal.

In drinking water use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once reconstituted: 2 hours

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.

Do not freeze.

Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

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

LABORATORIOS CALIER, S.A.

c/o. Barcelonés 26. Pla del Ramassa

08520LES FRANQUESES DEL VALLES, (Barcelona).

SPAIN

Tel.: +34 (0) 938495133

E-mail: Laboratorios@calier.es

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
{1x 1,000 doses}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN GUMBORO W2512 Lyophilisate for use in drinking water for chickens

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose contains:

Live attenuated avian infectious bursal disease (IBD) virus, intermediate plus IBDV_2512 strain, 1.5 - 3.0 log₁₀ EID₅₀*

* EID₅₀ (embryo infectious dose 50%)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1x 1,000 doses

4. ROUTE(S) OF ADMINISTRATION

In drinking water use.

5. WITHDRAWAL PERIOD

Withdrawal period: zero days

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

EXP {month/year}

Once reconstituted: 2 hours

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.