

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

{Boxes with 1 vial, boxes with 10 vials}

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

Primun Bronchitis H120 lyophilisate for suspension for chickens

Lyophilisate for suspension

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

**Each dose contains:**

Live attenuated Avian Infectious Bronchitis Virus (IB) Massachusetts *IBV\_H120* strain, 3.0 - 4.0 log<sub>10</sub> EID<sub>50</sub>\*

\* EID<sub>50</sub> (embryo infectious dose 50%)

**3. PHARMACEUTICAL FORM**

Lyophilisate for suspension.

**4. PACKAGE SIZE**

1x 1,000 doses

1x 2,000 doses

10x 1,000 doses

10x 2,000 doses

**5. TARGET SPECIES**

Chickens

**6. INDICATION(S)**

Read the package leaflet before use.

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

Dosage: 1 dose / animal

For oculo-nasal use, nebulisation use or in drinking water use.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Zero days.

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

Read the package before use.

**10. EXPIRY DATE**

EXP {month/year}

Once reconstituted used within 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.

The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory, see package leaflet for further information

Administration by a veterinary surgeon or on under their direct responsibility

**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.

Calle Barcelones, 26 Pla de Ramassar

08520 LES FRANQUESES DEL VALLÈS (Barcelona).

SPAIN

**16. MARKETING AUTHORISATION NUMBER(S)****17. MANUFACTURER'S BATCH NUMBER**

<Batch><Lot> {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**  
**{Boxes with 1 vial, boxes with 10 vials}**

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

Primun Bronchitis H120 lyophilisate for suspension for chickens

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

**Each dose contains:**

Live attenuated Avian Infectious Bronchitis Virus (IB) Massachusetts *IBV\_H120* strain, 3.0 - 4.0 log<sub>10</sub> EID<sub>50</sub>\*

\* EID<sub>50</sub> (embryo infectious dose 50%)

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

vials of 1,000 doses

vials of 2,000 doses

**4. ROUTE(S) OF ADMINISTRATION**

For oculo-nasal use, nebulisation use or in drinking water use.

**5. WITHDRAWAL PERIOD**

Zero days

**6. BATCH NUMBER**

<Batch><Lot> {number}

**7. EXPIRY DATE**

EXP month/year

Once reconstituted used by 2 hours

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.