

**ANNEXE III**

**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

1. Cardboard box with printing:  
1x 5 doses – glass vial 1 x 5 doses of lyophilised vaccine + 1x10 ml of Solvent)
2. Plastic box with a lid with 10 holes:  
5 x 5 doses – 5 x 5 doses of lyophilised vaccine + 5x10 ml of Solvent)

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

BOVALTO RESPI INTRANASAL, nasal spray, lyophilisate and solvent for suspension  
In SE NO DK: BOVALTO RESPI 2, nasal spray, lyophilisate and solvent for suspension

### **2. STATEMENT OF ACTIVE SUBSTANCES**

#### **1 dose (2 ml):**

#### **Lyophilisate:**

Bovine parainfluenza 3 virus (PI3V), modified live virus, strain Bio 23/A  $10^{5.0} - 10^{7.5} \text{TCID}_{50}$   
Bovine respiratory syncytial virus (BRSV), modified live virus, strain Bio 24/A  $10^{4.0} - 10^{6.0} \text{TCID}_{50}$

### **3. PHARMACEUTICAL FORM**

Nasal spray, lyophilisate and solvent for suspension

### **4. PACKAGE SIZE**

1 x 5 doses of lyophilised vaccine + 1x10 ml of Solvent  
5 x 5 doses of lyophilised vaccine + 5x10 ml of Solvent

### **5. TARGET SPECIES**

Cattle



### **6. INDICATION**

For the active immunization of calves from the age of 10 days against BRSV and PI3V, to reduce the quantity and duration of nasal excretion of both viruses.

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

Nasal use. Read the package leaflet before use.

**8. WITHDRAWAL PERIOD (S)**

Withdrawal period: Zero days.

**9. SPECIAL WARNING, IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP: {month/year}

Shelf life after reconstitution: 2 hours

**11. SPECIAL STORAGE CONDITIONS**

Store and transport refrigerated.

Do not freeze.

Protect from direct sunlight.

Store the reconstituted vaccine below 25°C.

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

Disposal: read package leaflet.

**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**

To be completed nationally.

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

To be completed nationally.

**17. MANUFACTURER'S BATCH NUMBER**

Lot:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**  
**5 doses** (glass vial of lyophilized vaccine)

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

BOVALTO RESPI INTRANASAL - Lyophilisate  
In SE NO DK: BOVALTO RESPI 2 - Lyophilisate



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

Read the package leaflet before use.

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

5 doses

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

Nasal use.

**5. WITHDRAWAL PERIOD(S)**

Withdrawal period: Zero days.

**6. BATCH NUMBER**

Lot:

**7. EXPIRY DATE**

EXP {month/year}  
Shelf life after reconstitution: 2 hours

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

5 doses (10 ml glass vial with 10 ml of solvent)

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

BOVALTO RESPI INTRANASAL - Solvent  
In SE NO DK: BOVALTO RESPI 2 - Solvent

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

Read the package leaflet before use.

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

10 ml

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

Nasal use.

**5. WITHDRAWAL PERIOD(S)**

Withdrawal period: Zero days.

**6. BATCH NUMBER**

Lot

**7. EXPIRY DATE**

EXP {month/year}

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

For animal treatment only.