A. LABELLING
PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND
THE IMMEDIATE PACKAGE
1x10 ml, 10x10 ml, 1x50 ml, 1x100 ml/ cardboard box
10x10 ml / covered plastic box with 10 cavities
100 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
BOVALTO Respi 4 suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES
1 dose (2ml):
Inactivated bovine respiratory syncytial virus, strain BIO-24 RP* ≥ 1
Inactivated bovine parainfluenza 3 virus, strain BIO-23 RP* ≥ 1
Inactivated bovine viral diarrhea virus, strain BIO-25 RP* ≥ 1
Inactivated *Mannheimia haemolytica*, serotype A1 strain DSM 5283 RP* ≥ 1
*Relative potency

3. PHARMACEUTICAL FORM
Suspension for injection.

4. PACKAGE SIZE
1x10 ml
10x10 ml
1x50 ml
1x100 ml
100 ml

5. TARGET SPECIES
Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION
Subcutaneous use.
Read the package leaflet before use.
8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once opened use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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

Disposal: read package leaflet;*
*: mention not requested on the immediate label (100ml)

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.*
*: mention not requested on the immediate label (100ml)

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

To be completed locally

16. MARKETING AUTHORISATION NUMBER(S)

To be completed locally
17. MANUFACTURER’S BATCH NUMBER

Lot
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle: 10 ml, 50 ml

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

   BOVALTO Respi 4 suspension for injection

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
   50 ml

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

   SC

5. **WITHDRAWAL PERIOD(S)**

   Withdrawal period(s): Zero days.

6. **BATCH NUMBER**

   Lot

7. **EXPIRY DATE**

   EXP {month/year}
   Once opened use within 10 hours.

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

   For animal treatment only.