A. LABELLING

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CN

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BLUEVAC-4, suspension for injection for sheep and cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of vaccine contains:

Active substance:
Bluetongue virus inactivated, serotype 4,
strain BTV-4/SPA-1/2004 .... $10^{6.5}$ $CCID_{50}$*

Aluminium hydroxide, purified saponin (Quil A), thiomersal

*See package leaflet

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 mL
100 mL
250 mL

5. TARGET SPECIES

Sheep and cattle

6. INDICATION(S)

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Shake well before 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 opened, use within 10 hours

11.	**SPECIAL STORAGE CONDITIONS**

Store and transport refrigerated (between 2ºC and 8ºC). Protect from light. Do not freeze.

12.	**SPECIAL 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 THESIGHT AND REACH OF CHILDREN"**

Keep out of the sight and reach of children.

15.	**NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

CZ Veterinaria, S.A.
La Relva s/n - Torneiros
36410 Porriño (España)

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

1704 ESP

17.	**MANUFACTURER'S BATCH NUMBER**

Batch: {number}

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CN

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1704 ESP

| 17. | MANUFACTURER'S BATCH NUMBER |

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BLUEVAC-4, suspension for injection for sheep and cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE

Each ml of vaccine contains:
Bluetongue virus inactivated, serotype 4,
strain BTV-4/SPA-1/2004 .... $10^{6.5}$ $CCID_{50}$

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

50 ml

4. ROUTE OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

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

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only