

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 1 bottle of 10 doses (1 x 10 ml)

Box of 1 bottle of 50 doses (1 x 50 ml)

Box of 1 bottle of 100 doses (1 x 100 ml)

Box of 10 bottles of 10 doses (10 x 10 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioBos BTV 3 suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml dose contains:

Bluetongue virus, serotype 3, inactivated

10 - 320 ELISA units

3. PACKAGE SIZE

10 doses (10 ml)

50 doses (50 ml)

100 doses (100 ml)

10 x 10 doses (10 x 10 ml)

4. TARGET SPECIES

Sheep, cattle.



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Sheep: subcutaneous use.

Cattle: intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {dd/mm/yyyy}

Once broached, use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”
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Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”
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For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”
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Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bioveta a.s.
{Bioveta logo}

14. AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 10 ml

Bottle of 50 ml

Bottle of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioBos BTV 3



{Bioveta logo}

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

BTV3

10 doses (10 ml)

50 doses (50 ml)

100 doses (100 ml)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

Once broached, use within 10 hours.