

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{1 x 5 doses/carton; 2 x 1 dose, 5 x 1 dose, 10 x 1 dose, 10 x 5 doses/plastic box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioEquin FT suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml dose contains:

Active substances:

Influenza A virus, subtype H3N8, strain A/equine/Limerick/2010, inactivated

Influenza A virus, subtype H3N8, strain A/equine/Brno/08, inactivated

min. 5 log₂ HIT

min. 5 log₂ HIT

Clostridium tetani, strain Harvard 49205, tetanus toxoid

min. 30 IU

3. PACKAGE SIZE

2 x 1 dose

5 x 1 dose

10 x 1 dose

1 x 5 doses

10 x 5 doses

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use by 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.

Protect from frost.

Protect from light.

Store in a dry place.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bioveta, a. s.
{logo Bioveta}

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{1 dose; 5 doses/label on a glass vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioEquin FT



{logo Bioveta}

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

EIV, two H3N8 strains, inactivated
Tetanus toxoid

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use by 10 hours.

1 dose

5 doses

