

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton 1 x 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NALGOSED 10 mg/ml solution for injection
Butorphanol

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Active substance:

Butorphanol (as butorphanol tartrate) 10 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

Horses, dogs, cats.



6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Horse: Strictly intravenous use.

Dog, cat: intravenous, subcutaneous or intramuscular use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Horses:

Meat and offal: Zero days.

Milk: Zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Accidental injection is dangerous and requires immediate medical attention.

10. EXPIRY DATE

EXP: {month/year}

Once opened use within 28 days.

11. SPECIAL STORAGE CONDITIONS

Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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

Bioveta, a.s.
Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NALGOSED 10 mg/ml solution for injection
Butorphanol

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Active substance:
Butorphanol (as butorphanol tartrate) 10 mg/ml

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

10 ml

4. ROUTE(S) OF ADMINISTRATION

Horse: Strict IV
Dog, cat: IV, SC or IM

5. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Horses:
Meat and offal: Zero days.
Milk: Zero hours.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP: {month/year}
Once opened use within:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

