

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardbord box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spasmipur 20 mg/ml solution for injection
(AT, BE, BG, CZ, DE, EE, EL, ES, HR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SI, SK, UK)

Spasmipur vet. 20 mg/ml solution for injection
(DK, FI, IS, NO, SE)

Spasmipur solution for injection
(FR)

Hyoscine butylbromide

2. STATEMENT OF ACTIVE SUBSTANCES

Hyoscine butylbromide 20 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Horses, cattle, sheep, pigs

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous and intramuscular use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:

Meat and offal:

Horse	3 days
Cattle	2 days
Sheep	18 days
Pig	9 days

Milk:

Horse, Cattle and Sheep 12 hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once broached use within 28 days.

11. SPECIAL STORAGE CONDITIONS

After first opening do not store above 25 °C.

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 THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH, 4600 Wels, AUSTRIA

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml colourless glass vial with bromobutyl rubber stopper and aluminium cap

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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Spasmipur vet. 20 mg/ml solution for injection
(DK, FI, IS, NO, SE)

Spasmipur solution for injection
(FR)

Hyoscine butylbromide

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Hyoscine butylbromide 20 mg/ml

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

Intravenous and intramuscular use

5. WITHDRAWAL PERIOD**Withdrawal period:**Meat and offal:

Horse	3 days
Cattle	2 days
Sheep	18 days
Pig	9 days

Milk:

Horse, Cattle and Sheep 12 hours

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 28 days.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.