*[Version 9,03/2022] corr. 11/2022*

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spasmipur 20 mg/ml solution for injection for horses, cattle, sheep and pigs
(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 for horses, cattle, sheep and pigs
(DK, FI, IS, NO, SE)

Spasmipur solution for injection for horses, cattle, sheep and pigs
(FR)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substance:**
Hyoscine butylbromide 20 mg
(equivalent to 13.8 mg hyoscine)

**Excipients:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Benzyl alcohol (E1519) | 20 mg |
| Water for injection | |

Clear, colourless to slightly yellow solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Horses, cattle, sheep and pigs

### 3.2 Indications for use for each target species

Treatment of acute spasms of the gastrointestinal tract (colic) and of the urinary tract.
As an aid in procedures for which reduced peristaltic activity of the gastrointestinal tract or reduced contractions in the urinary tract are required.

### 3.3 Contraindications

Do not use in case of paralytic ileus, mechanical obstruction, or cardiac disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in horses with glaucoma.
Do not use in horses less than 6 weeks of age.

### 3.4 Special warnings

None.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

Horses should be monitored carefully following treatment.
The treatment is essentially symptomatic and an appropriate handling of the underlying disorder is necessary.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to hyoscine butylbromide or benzyl alcohol should avoid contact with the veterinary medicinal product.

Accidental self-injection may result in cardiac and circulatory effects. Avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

The veterinary medicinal product can cause skin and eye irritation. Avoid contact with skin and eyes. In the case of contact with skin, wash with soap and water. If irritation persists, seek medical advice. Wash hands after use.
If the veterinary medicinal product comes into contact with the eyes, rinse the eyes immediately with plenty of water and seek medical attention if irritation persists.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Horses:

| | |
|---|---|
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Tachycardia |
| Undetermined frequency (cannot be estimated from the available data): | Colic[1] |

[1] Due to inhibition of motility.

Cattle, sheep, pigs:

| | |
|---|---|
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Tachycardia |

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Laboratory studies in mice have not produced any evidence of teratogenic effects. No information on use during pregnancy in the target species is available. An effect upon the smooth muscles of the birth canal can occur.

Hyoscine butylbromide, like all other anticholinergic agents, can inhibit the production of milk. Due to its low solubility in fat, excretion of hyoscine butylbromide in milk is very low.
Use only according to the benefit-risk assessment by the responsible veterinarian.

### 3.8 Interaction with other medicinal products and other forms of interaction

This veterinary medicinal product may enhance the tachycardic effects of beta-adrenergic drugs and may alter the effect of other drugs, such as digoxin.
The effects of hyoscine butylbromide may be potentiated by the concomitant use of other anticholinergic drugs. Co-administration with other anticholinergic or parasympatholytic drugs should be avoided.

### 3.9 Administration routes and dosage

For intravenous or intramuscular use.

| | |
|---|---|
| Horses, cattle and pigs: | 0.2 - 0.4 mg of hyoscine butylbromide/kg body weight by intravenous injection (equivalent to 0.1 - 0.2 ml of the veterinary medicinal product/10 kg body weight). |
| Sheep: | 0.7 mg of hyoscine butylbromide/kg body weight by intravenous injection (equivalent to 0.35 ml of the veterinary medicinal product/10 kg body weight). |

<u>To reduce contractions of the smooth muscle in the gastrointestinal or urinary tract (spasmolytic effect):</u>
If necessary, treatment can be repeated once at 12 hours after initial administration according to the veterinarian criteria.
Only in cases where intravenous injection is not possible, the veterinary medicinal product may be administered intramuscularly at the higher dose specified for the respective target species.

<u>For clinical procedures (see indications for use):</u>
Administer immediately before inactivity in the gastrointestinal or urinary tract is required.
For clinical procedures use intravenous administration only.

A slow injection when using either the intravenous or the intramuscular route is recommended.

To ensure a correct dosage, body weight should be determined as accurately as possible and dosing devices or syringes with suitable graduations are to be used.

The rubber stopper can be punctured a maximum of 25 times.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose, anticholinergic symptoms, such as urinary retention, thirst, tachycardia, inhibition of gastrointestinal motility and transient visual disturbances may occur.
If necessary, parasympathomimetic drugs can be administered. In addition, appropriate supportive measures should be used as required.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

### 3.12 Withdrawal periods

<u>Meat and offal:</u>
Horses 3 days

Cattle 2 days
Sheep 18 days
Pigs 9 days

Milk:
Horses, Cattle and Sheep 12 hours

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QA03BB01

### 4.2 Pharmacodynamics

Hyoscine butylbromide is a quaternary ammonium compound of scopolamine and is an antispasmodic agent which relaxes smooth muscle of the organs of the abdominal and pelvic cavities. It is believed to act predominantly on the intramural parasympathetic ganglia of these organs. Hyoscine butylbromide antagonises the actions of acetylcholine mediated through the muscarinic receptor. It also has some antagonist effect at nicotinic receptors. Due to its chemical structures as a quaternary ammonium derivative, hyoscine butylbromide is not expected to enter the central nervous system and, therefore, does not produce secondary anticholinergic effects in the central nervous system.

### 4.3 Pharmacokinetics

In all species, peak concentrations are reached within a few minutes of parenteral drug administration. Hyoscine butylbromide is rapidly distributed into the tissues, achieving the highest concentrations in the liver and kidneys. It is rapidly excreted in all species. Hyoscine butylbromide does not cross the blood-brain barrier.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months
Shelf life after first opening the immediate packaging: 28 days

### 5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
After first opening the immediate packaging, do not store above 25 °C.

### 5.4 Nature and composition of immediate packaging

Cardboard box with colourless glass vial type II (Ph. Eur.). Bromobutyl rubber stopper, type I (Ph. Eur.) and pull off aluminium cap or flip off aluminium/plastic cap.

Pack size:
Cardboard box with 1 vial of 50 ml.

### 5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH

## 7. MARKETING AUTHORISATION NUMBER(S)

## 8. DATE OF FIRST AUTHORISATION

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**
Cardboard 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

Each ml contains:
Hyoscine butylbromide 20 mg

## 3. PACKAGE SIZE

50 ml

## 4. TARGET SPECIES

Horses, cattle, sheep, pigs

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Intravenous and intramuscular use.

## 7. WITHDRAWAL PERIODS

**Withdrawal period:**
Meat and offal:
Horses 3 days
Cattle 2 days
Sheep 18 days
Pigs 9 days

Milk:
Horses, Cattle and Sheep 12 hours

## 8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.
Use by:

## 9. SPECIAL STORAGE PRECAUTIONS

After first opening do not store above 25 °C.

## 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

VetViva Richter (logo)

## 14. MARKETING AUTHORISATION NUMBERS

## 15. 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

Spasmipur
(AT, BE, BG, CZ, DE, EE, EL, ES, FR, HR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SI, SK, UK)

Spasmipur vet.
(DK, FI, IS, NO, SE)

Horses, cattle, sheep and pigs

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Hyoscine butylbromide 20 mg/ml

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days. …….
Use by:
50 ml
VetViva Richter (logo)

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Spasmipur 20 mg/ml solution for injection for horses, cattle, sheep and pigs
(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 for horses, cattle, sheep and pigs
(DK, FI, IS, NO, SE)

Spasmipur solution for injection for horses, cattle, sheep and pigs
(FR)

## 2. Composition

Each ml contains:

**Active substance:**
Hyoscine butylbromide 20 mg
(equivalent to 13.8 mg hyoscine)

**Excipients:**
Benzyl alcohol (E1519) 20 mg

Clear, colourless to slightly yellow solution.

## 3. Target species

Horses, cattle, sheep and pigs

## 4. Indications for use

Treatment of acute spasms of the gastrointestinal tract (colic) and of the urinary tract.
As an aid in procedures for which reduced peristaltic activity of the gastrointestinal tract or reduced contractions in the urinary tract are required.

## 5. Contraindications

Do not use in case of paralytic ileus, mechanical obstruction, or cardiac disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in horses with glaucoma.
Do not use in horses less than 6 weeks of age.

## 6. Special warnings

Special precautions for safe use in the target species :
Horses should be monitored carefully following treatment.
The treatment is essentially symptomatic and an appropriate handling of the underlying disorder is necessary.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to hyoscine butylbromide or benzyl alcohol should avoid contact with the veterinary medicinal product.
Accidental self-injection may result in cardiac and circulatory effects. Avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
The veterinary medicinal product can cause skin and eye irritation. Avoid contact with skin and eyes. In the case of contact with skin, wash with soap and water. If irritation persists, seek medical advice. Wash hands after use.
If the veterinary medicinal product comes into contact with the eyes, rinse the eyes immediately with plenty of water and seek medical attention if irritation persists.

Pregnancy and lactation:
Laboratory studies in mice have not produced any evidence of teratogenic effects. No information on use during pregnancy in the target species is available. An effect upon the smooth muscles of the birth canal can occur.
Hyoscine butylbromide, like all other anticholinergic agents, can inhibit the production of milk. Due to its low solubility in fat, excretion of hyoscine butylbromide in milk is very low.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
This veterinary medicinal product may enhance the tachycardic effects of beta-adrenergic drugs and may alter the effect of other drugs, such as digoxin.
The effects of hyoscine butylbromide may be potentiated by the concomitant use of other anticholinergic drugs. Co-administration with other anticholinergic or parasympatholytic drugs should be avoided.

Overdose :
In case of overdose, anticholinergic symptoms, such as urinary retention, thirst, tachycardia, inhibition of gastrointestinal motility and transient visual disturbances, may occur.
If necessary, parasympathomimetic drugs can be administered. In addition, appropriate supportive measures should be used as required.

Special restrictions for use and special conditions for use:

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

## 7. Adverse events

**Horses:**
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Tachycardia (rapid heart rate)

Undetermined frequency (cannot be estimated from the available data):
Colic[1]
[1] Due to inhibition of motility.

**Cattle, sheep, pigs:**
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Tachycardia (rapid heart rate)

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the

medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

## 8. Dosage for each species, routes and method of administration

For intravenous or intramuscular use.

Horses, cattle and pigs: 0.2 - 0.4 mg of hyoscine butylbromide/kg body weight by intravenous injection (equivalent to 0.1 - 0.2 ml of the veterinary medicinal product/10 kg body weight).

Sheep: 0.7 mg of hyoscine butylbromide/kg body weight by intravenous injection (equivalent to 0.35 ml of the veterinary medicinal product/10 kg body weight).

To reduce contractions of the smooth muscle in the gastrointestinal or urinary tract (spasmolytic effect):
If necessary, the treatment can be repeated once at 12 hours after initial administration according to the veterinarian criteria.
Only in cases where intravenous injection is not possible, the veterinary medicinal product may be administered intramuscularly at the higher dose specified for the respective target species.

For clinical procedures (see indications for use):
Administer immediately before inactivity in the gastrointestinal or urinary tract is required.
For clinical procedures use intravenous administration only.

A slow injection when using either the intravenous or the intramuscular route is recommended.

To ensure administration of a correct dosage, body weight should be determined as accurately as possible and dosing devices or syringes with suitable graduations are to be used.

The rubber stopper can be punctured a maximum of 25 times.

## 9. Advice on correct administration

See “Special warnings” in the package leaflet.

## 10. Withdrawal periods

Meat and offal:

| | |
|---|---|
| Horses | 3 days |
| Cattle | 2 days |
| Sheep | 18 days |
| Pigs | 9 days |

Milk:
Horses, Cattle and Sheep 12 hours

## 11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.
After first opening the immediate package do not store above 25 °C.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after "Exp.". The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 14. Marketing authorisation numbers and pack sizes

XXXXXXXXXX

**Pack size:**
Cardboard box with 1 vial of 50 ml.

## 15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## 16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse reactions>:
VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

<Local representatives <and contact details to report suspected adverse reactions>:>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>

## <17. Other information>