

[Version 8.1,01/2017]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

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)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Hyoscine butylbromide (equivalent to 13.8 mg hyoscine)	20 mg
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Excipients:

Benzyl alcohol (E1519)	20 mg
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For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear, colourless to slightly yellow solution

4. CLINICAL PARTICULARS

4.1 Target species

Horses, cattle, sheep and pigs

4.2 Indications for use, specifying the 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.

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 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 product comes into contact with the eyes, rinse the eyes immediately with plenty of water and seek medical attention if irritation persists.

4.6 Adverse reactions (frequency and seriousness)

On very rare occasions, tachycardia may occur.

In horses, the veterinary medicinal product may cause colic due to inhibition of motility.

The frequency of adverse reactions is defined using the following convention:

- Very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- Common (more than 1 but less than 10 animals in 100 animals treated)
- Uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- Rare (more than 1 but less than 10 animals in 10,000 animals treated)
- Very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy and lactation

Laboratory studies in mice have not produced any evidence of a teratogenic effect. 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.

4.8 Interaction with other medicinal products and other forms of interaction

This 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.

4.9 Amounts to be administered and administration route

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 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 product/10 kg body weight).

To reduce contractions of the smooth muscle in the gastrointestinal or urinary tract (spasmodic effect):

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.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Meat and offal:

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

Milk:

Horse, Cattle and Sheep 12 hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Drugs for functional gastrointestinal disorders, belladonna derivatives, plain, butylscopolamine. ATC vet code: QA03BB01.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Water for injection

6.2 Major incompatibilities

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

6.3 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

6.4. Special precautions for storage

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

6.5 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 or flip off aluminium cap.
Pack size: Cardboard box with 1 vial of 50 ml.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH
Durisolstrasse 14
4600 Wels
AUSTRIA

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE