[Version 8.1,01/2017]

PACKAGE LEAFLET:

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)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Richter Pharma AG, Feldgasse 19, 4600 Wels, Austria

Manufacturer responsible for batch release:
Richter Pharma AG, Durisolstrasse 14, 4600 Wels, Austria

2. 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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

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

Excipiens:
Benzyl alcohol (E1519) 20 mg

Clear, colourless to slightly yellow solution

4. INDICATION(S)

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. ADVERSE REACTIONS

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

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 inform your veterinary surgeon.

7. TARGET SPECIES

Horses, cattle, sheep and pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 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).

<u>To reduce contractions of the smooth muscle in the gastrointestinal or urinary tract (spasmolytic effect):</u>
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.

<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 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 PERIOD(S)

Meat and offal:

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

Milk:

Horse, 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 before first opening.
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 container: 28 days
After first opening do not store above 25 °C.

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

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.

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 accordingly to the benefit-risk assessment by the responsible veterinarian.

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.

Overdose (symptoms, emergency procedures, 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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{DD/MM/YYYY}

15. OTHER INFORMATION

Pack size:
Cardboard box with 1 vial of 50 ml.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.