ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spasmium comp. 500 mg/ml + 4 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Metamizole sodium monohydrate 500.0 mg
(equivalent to 443 mg metamizole)

Hyoscine butylbromide 4.0 mg
(equivalent to 2.76 mg hyoscine)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
5 x 100 ml

5. TARGET SPECIES

Horses, cattle, pigs, dogs

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous or intramuscular.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal:

Horse, cattle (IV)	12 days
Pig (IM)	15 days

Milk:

Cattle (IV)	96 hours

Not authorised for use in mares producing milk for human consumption.

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, Durisolstrasse 14, 4600 Wels, Austria

16. MARKETING AUTHORISATION NUMBER(S)

Vm 57446/4005

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Label of 100 ml amber glass vial (type II) with bromobutyl rubber stopper and aluminium cap

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spasmium comp. 500 mg/ml + 4 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Metamizole sodium monohydrate	500.0 mg/ml
Hyoscine butylbromide	4.0 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Horses, cattle, pigs, dogs

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous or intramuscular.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal:

Horse, cattle (IV)	12 days
Pig (IM)	15 days

Milk:

Cattle (IV)	96 hours

Not authorised for use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use by …

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

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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, Durisolstrasse 14, 4600 Wels, Austria

16. MARKETING AUTHORISATION NUMBER(S)

Vm 57446/4005

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Spasmium comp. 500 mg/ml + 4 mg/ml solution for injection

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

Marketing authorisation holder:
VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spasmium comp. 500 mg/ml + 4 mg/ml solution for injection

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

Each ml contains:

Active substances:
Metamizole sodium monohydrate 500.0 mg
(equivalent to 443 mg metamizole)

Hyoscine butylbromide 4.0 mg
(equivalent to 2.76 mg hyoscine)

Excipients:
Phenol (as preservative) 5.0 mg

Clear, yellowish solution.

4. INDICATION(S)

Horses, cattle, pigs, dogs: Treatment of spasms or sustained increased tonus of smooth muscles of the gastro-intestinal tract or of the urine and bile excretory organs associated with pain.

Horses only: Spasmodic colics.

Cattle, pigs, dogs only: As supportive therapy for acute diarrhoea.

5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to the active substances or to any of the excipients.

Do not use in cases of:
- gastro-intestinal ulceration
- chronic gastro-intestinal disorders
- mechanic stenoses in the gastro-intestinal system
- paralytic ileus in horses
- disorders of the haematopoietic system
- blood clotting disorders
- renal insufficiency
- tachyarrhythmia
- glaucoma
- prostate adenoma.

6. ADVERSE REACTIONS

In horses and cattle, a slight increase in heart rate may be observed occasionally due to the inhibitory effect of hyoscine butylbromide on the parasympathetic system.
In dogs painful reactions at the injection site can occur immediately after injection, which abate rapidly and have no negative impact on the expected therapeutic benefit.
In very rare cases, anaphylactic reactions may occur and should be treated symptomatically.
Based on pharmacological properties of hyoscine butylbromide, dryness of mucous membranes, paralytic ileus, constipation and urinary retention may occur.

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, pigs, dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Horse, cattle: intravenous use
Pig: intramuscular use
Dog: intravenous or intramuscular use

Dosage instruction:

Horse: 25 mg metamizole sodium monohydrate/kg body weight and
0.2 mg hyoscine butylbromide/kg body weight (i.e. 2.5 ml per 50 kg)

Cattle: 40 mg metamizole sodium monohydrate/kg body weight and

0.32 mg hyoscine butylbromide/kg body weight (i.e. 4 ml per 50 kg)

Calf: 50 mg metamizole sodium monohydrate/kg body weight and 0.4 mg hyoscine butylbromide/kg body weight (i.e. 1 ml per 10 kg)

Pig: 50 mg metamizole sodium monohydrate/kg body weight and 0.4 mg hyoscine butylbromide/kg body weight (i.e. 1 ml per 10 kg)

Dog: 50 mg metamizole sodium monohydrate/kg body weight and 0.4 mg hyoscine butylbromide/kg body weight (i.e. 0.1 ml per kg)

Treatment frequency:
Cattle and calves: up to twice daily for three days.
Horses and pigs: single injection.
Dogs: single injection. Treatment can be repeated after 24 hours if necessary.

The stopper must not be punctured more than 25 times.

9. ADVICE ON CORRECT ADMINISTRATION

See section “Special warnings”.

10. WITHDRAWAL PERIOD(S)

Meat and offal:

Horse, cattle (IV)	12 days
Pig (IM)	15 days

Milk:

Cattle (IV)	96 hours

Not authorised for use in mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the vial and carton label 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 the immediate packaging do not store above 25°C.

12. SPECIAL WARNING(S)

Special warnings for each target species
None.

Special precautions for use in animals
Due to the risk of anaphylactic shock metamizole-containing solutions should be administered slowly when given intravenously.

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

In a very small number of people, metamizole can cause reversible, but potentially serious agranulocytosis and other reactions such as skin allergy. Take care to avoid self-injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to metamizole or hyoscine butylbromide should avoid contact with the veterinary medicinal product. Avoid use of the product if you are known to be sensitive to pyrazolones, or are sensitive to acetylsalicylic acid.

Wash splashes from skin and eyes immediately.

Pregnancy and lactation

Studies in laboratory animals (rabbit, rat) have not produced any evidence of a toxic effect on reproduction. No information on use during pregnancy in the target species is available. An effect upon the smooth muscles of the birth canal can occur. Metabolites of metamizole cross the placental barrier and penetrate into milk. Therefore this product should be used only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

The effects of metamizole and/or hyoscine butylbromide may be potentiated by concurrent use of other anticholinergic or analgesic substances.

Concomitant use of inducers of hepatic microsomal enzymes (e.g. barbiturates, phenylbutazone) reduces the half-life period and hence the duration of action of metamizole. Simultaneous administration of neuroleptics, especially phenothiazine derivatives, may lead to severe hypothermia. Furthermore the risk of gastro-intestinal bleeding is increased upon concurrent use of glucocorticoids. The diuretic effect of furosemide is attenuated.

Co-administration of other weak analgesics increases the effects and side-effects of metamizole.

The anticholinergic action of chinidin and antihistaminics as well as the tachycardic effects of β-sympathomimetics may be enhanced by this veterinary medicinal product.

Overdose (symptoms, emergency procedures, antidotes)

The acute toxicity of both active substances is very low. In studies with rats the symptoms were non-specific and included: ataxia, dilation of pupils, increased heart rate, exhaustion, convulsions, unconsciousness and respiratory signs.

In case of overdosage treatment should be discontinued. Physostigmin is recommended as an antidote to hyoscine butylbromide. A specific antidote for metamizole sodium is not available. Therefore symptomatic treatment should be initiated in case of overdosage.

Due to the inhibitory effect of hyoscine butylbromide on the parasympathetic system a slight increase in the heart rate was observed in some cases in horses and cattle following administration of the double therapeutic dose.

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.

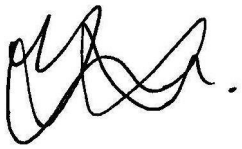
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2023

15. OTHER INFORMATION

Pack sizes: 100 ml, 5 x 100 ml
Not all pack sizes may be marketed.

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



Approved: 23 January 2023