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. PACKAGE SIZE

100 ml
5 x 100 ml

4. TARGET SPECIES

Horses, cattle, pigs, dogs

5. INDICATIONS

-

6. ROUTES OF ADMINISTRATION

Horses, cattle: i.v./Pigs: i.m./Dogs: i.m.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal:
Horses, cattle (i.v.) 12 days
Pigs (i.m.) 15 days

Milk:
Cattle (i.v.) 96 hours

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.
Once broached, use by…

9. SPECIAL STORAGE PRECAUTIONS

After first opening the immediate packaging 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

14. MARKETING AUTHORISATION NUMBERS

Vm 57446/5008

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (100 ml amber glass vial)

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. TARGET SPECIES

Horses, cattle, pigs, dogs

4. ROUTES OF ADMINISTRATION

Horses, cattle: i.v./Pigs: i.m./Dogs: i.m.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal:
Horses, cattle (i.v.)12 days
Pigs (i.m.) 15 days

Milk:
Cattle (i.v.) 96 hours

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

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days

Once broached, use by…

7. SPECIAL STORAGE PRECAUTIONS

After first opening the immediate packaging do not store above 25°C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter

9. BATCH NUMBER

Lot {number}

100 ml

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Spasmium comp. 500 mg/ml + 4 mg/ml solution for injection for horses, cattle, pigs and dogs

2. Composition

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 for injection.

3. Target species

Horses, cattle, pigs, dogs

4. Indications for use

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:
Spasmodic colics.

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

5. Contraindications

Do not use in 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. Special warnings

Special precautions for safe use in the target species:
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 veterinary medicinal 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:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Laboratory studies in rabbits and rats have not produced any evidence of teratogenic effects. An effect upon the smooth muscles of the birth canal can occur. Metabolites of metamizole cross the placental barrier and penetrate into milk. Use 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:
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.

<Special restrictions for use and special conditions for use:>
(to be completed in accordance with national requirements)

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, cattle, pigs, dogs:
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylactic-type reaction[1]

Undetermined frequency (cannot be estimated from the available data):
Increased heart rate[2]; Dry mucous membrane[3]; Paralytic ileus[3], Constipation[3]; Urinary retention[3]; Injection site pain[4].

[1]Should be treated symptomatically.
[2]In horses and cattle. Slightly. Due to the inhibitory effect of hyoscine butylbromide on the parasympathetic system.
[3]Based on pharmacological properties of hyoscine butylbromide.
[4]In dogs. Can occur immediately after injection, which abate rapidly without negative impact on the expected therapeutic benefit.

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 at https://www.gov.uk/report-veterinary-medicine-problem.

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

Intravenous use (i.v.): horses, cattle, dogs.
Intramuscular use (i.m.): pigs, dogs.

Dosage instruction:

Horses (i.v.):	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 (i.v.):	40 mg metamizole sodium monohydrate/kg body weight and 0.32 mg hyoscine butylbromide/kg body weight (i.e. 4 ml per 50 kg)
Calves (i.v.):	50 mg metamizole sodium monohydrate/kg body weight and 0.4 mg hyoscine butylbromide/kg body weight (i.e. 1 ml per 10 kg)
Pigs (i.m.):	50 mg metamizole sodium monohydrate/kg body weight and 0.4 mg hyoscine butylbromide/kg body weight (i.e. 1 ml per 10 kg)
Dogs (i.v. or i.m.):	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 periods

Meat and offal:

Horses, cattle (i.v.)	12 days
Pigs (i.m.)	15 days

Milk:

Cattle (i.v.)	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 precautions for disposal

Medicines should not be disposed of via wastewater.

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

Vm 57446/5008

Amber type II glass vials closed with a bromobutyl rubber stopper, sealed with an aluminum cap and packaged in a cardboard box.

Pack sizes:
Cardboard box with 1 vial of 100 ml solution for injection.
Cardboard box with 5 vials of 100 ml solution of injection.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

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
adverse.events@vetviva.com
Tel: +43 664 8455326

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

17. Other information

POM-V	Veterinary medicinal product subject to prescription

Approved 27 November 2024

Gavin Hall