SUMMARY OF PRODUCT CHARACTERISTICS

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. QUALITATIVE AND QUANTITATIVE 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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Phenol (as preservative)	5.0 mg
Tartaric acid (E 334)	
Water for injections	

Clear, yellowish solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

Horses, cattle, pigs, dogs

3.2 Indications for use for each target species

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.

3.3 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
- coagulopathies
- renal insufficiency
- tachyarrhythmia
- glaucoma
- prostate adenoma.

3.4 Special warnings

None.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 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 parasympatholytic activity of hyoscine butylbromide.
[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 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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

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.

3.8 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.

3.9 Administration routes and dosage

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.

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

The acute toxicity of both active substances is very low. In studies with rats the symptoms were non-specific and included: ataxia, mydriasis, tachycardia, prostration, 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 parasympatholytic activity of hyoscine butylbromide a slight increase in the heart rate was observed in some cases in horses and cattle following administration of the double therapeutic dose.

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

(to be completed in accordance with national requirements)

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QA03DB04

4.2 Pharmacodynamics

Hyoscine butylbromide
The parasympatholytic agent hyoscine butylbromide antagonises the muscarinic actions of acetylcholine by competitive inhibition of acetylcholine at parasympathetic nerve endings. Activity at the nicotinic receptors occurs only at high (toxic) doses. It inhibits the contraction of smooth muscles of the gastro-intestinal tract and urine and bile excretory organs. Due to its quaternary ammonium structure, it cannot cross the blood-brain-barrier and therefore does not produce the central nervous effects of atropine.

Metamizole sodium
Metamizole belongs to the group of pyrazolone derivatives and is used as an analgesic, antipyretic and spasmolytic agent. It has significant central analgesic and antipyretic, but only low anti-inflammatory effect (weak analgesics). Metamizole inhibits the synthesis of prostaglandins by blocking the cyclooxygenase. The analgesic and antipyretic effect is mainly due to inhibition of prostaglandin E_2 synthesis. In addition, metamizole has a spasmolytic effect on smooth muscle organs. Metamizole sodium further antagonises the effects of bradykinin and histamine.

4.3 Pharmacokinetics

Hyoscine butylbromide
The quaternary ammonium structure confers poor absorption after oral administration and prevents the transition to CNS also after parenteral administration. 17 – 24% are bound to plasma proteins. Elimination half-life is 2 – 3 hours. Hyoscine butylbromide is excreted mostly unchanged via the kidneys. After parenteral administration

hyoscine butylbromide is mainly eliminated in urine (approx. 54%). Following oral administration only 1% of the administered dose is excreted in urine.

After intravenous injection the onset of action is immediate, after intramuscular injection it is delayed for 20 – 30 minutes. Depending on administration route and clinical picture the spasmolytic effect lasts for approximately 4 – 6 hours.

Metamizole sodium
Metamizole sodium is rapidly absorbed with an absolute bioavailability of approximately 100%. The primary metabolite of metamizole sodium in plasma and urine is the pharmacologically active 4-methyl-aminoantipyrine (MAA).
Other metabolites (4-acetyl-aminoantipyrine (AAA), 4-formyl-aminoantipyrine (FAA) and aminoantipyrine (AA)) are present in smaller quantities. Plasma protein binding of the metabolites is as follows: MAA: approx. 56%, AA: approx. 40%, FAA: approx. 15%, AAA: approx. 14%. The plasma half-life of MAA is about 6 hours. After oral or

intravenous administration metamizole sodium is primarily eliminated renally (50 – 70% of the dose, depending on species), in lactating animals also via milk.

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: 3 years
Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

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.

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

Vm 57446/3007

8. DATE OF FIRST AUTHORISATION

08 September 2015

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

July 2024

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).

Approved 27 November 2024
Gavin Hall