1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buscopan Compositum solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Butylscopolamine bromide 4 mg
Metamizole 500 mg

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 mg
Tartaric acid	
Water for injection	

A slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (adult), horses and dogs.

3.2 Indications for use for each target species

Horses: As an aid in the control of pain associated with simple colic and as a diagnostic aid in more severe colics.
Cattle, horses and dogs: For the control of diarrhoea, particularly when pain or abdominal discomfort is present.
Horses and dogs: For the control of pain associated with urinary obstruction.

3.3 Contraindications

Due to risk of local reactions do not use the intramuscular route in horses.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in horses suffering from paralytic ileus.

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:

Take care to avoid self-injection. In a very small number of people, metamizole can cause reversible, but potentially serious agranulocytosis and other reactions such as skin allergy.
People with known hypersensitivity to pyrazolones or aspirin should avoid contact with the veterinary medicinal product.
Wash any splashes from the skin.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, horses and dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylaxis[1] Circulatory shock[1]; Increased heart rate[2]

[1]May occur if the intravenous injection is administered too fast.
[2] In horses. Slight, and transient due to the parasympatholytic activity of butylscopolaminiumbromide.

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

Laboratory studies in rabbits and rats have not produced any evidence of teratogenic effects.
The safety of the veterinary medicinal product has not been established during pregnancy and therefore the use is not recommended.

3.8 Interaction with other medicinal products and other forms of interaction

The effects of metamizole and/or butylscopolamine bromide may be potentiated by concurrent use of other anticholinergic or analgesic drugs.
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 quinidine and antihistaminic as well as the tachycardic effects of β sympathomimetics may be enhanced by this veterinary medicinal product.

3.9 Administration routes and dosage

Horses: Intravenous use.
Cattle, dogs: Intravenous or intramuscular use.

Use aseptic techniques.

Horses: 5 ml per 100 kg body weight by intravenous injection only.
Cattle: 5 ml per 100 kg body weight by intravenous or intramuscular injection.
Dogs: 0.1 ml per kg body weight by intravenous or intramuscular injection.

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

The acute toxicity of both compounds is very low. In studies with rats the symptoms were non-specific and included ataxia, mydriasis, tachycardia, prostration, convulsions, coma and respiratory signs.

Symptomatic treatment should be initiated in case of overdosage.

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

Not applicable.

3.12 Withdrawal periods

Meat and offal:

Horses: 12 days.
Cattle: **i.v.** injection: 9 days.
i.m. injection: 28 days.

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QA03DB04

4.2 Pharmacodynamics

Butylscopolamine bromide is a spasmolytic agent with particular activity on the smooth muscle of the digestive and urinary systems. It antagonises the actions of acetylcholine at the muscarinic receptor and also has some activity at nicotinic receptors. Its pharmacological profile is similar to atropine, the main member of this class.

4.3 Pharmacokinetics

The quaternary ammonium structure confers poor absorption after oral administration and prevents penetration of the central nervous system after parenteral administration. 17-24% is plasma protein bound and plasma elimination half-life is 2-3 hours. It is excreted mostly unchanged - about 54% via the kidneys in urine after parenteral administration. After oral administration, only around 1% is excreted in urine.

Metamizole is a non-steroidal anti-inflammatory drug of the pyrazolone group and also has analgesic and anti-pyretic effects. It is rapidly absorbed with absolute bioavailability of nearly 100%. The primary metabolite in plasma and urine is 4-methyl-aminoantipyrine (MAA), which is pharmacologically active with a plasma half-life of around 6 hours. Other metabolites are present in smaller quantities. The metabolites are bound (to various degrees) to plasma proteins, with 56% MAA bound. Excretion occurs mainly via the kidney, with 50-70% of the dose eliminated in urine, depending on species.

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

Do not store above 25 °C.
Protect from light.
Keep the bottle in the outer carton.

5.4 Nature and composition of immediate packaging

Multidose amber 100ml Type II glass injection bottles with grey bromobutyl rubber stoppers and aluminium overseals.
Pack size: One 100 ml bottle in a cardboard box.

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

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10454/004/001

8. DATE OF FIRST AUTHORISATION

01/10/1991

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

30/06/2026

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).