PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Folding box (100ml)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buscopan Compositum Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substances:

Butylscopolamine bromide	4 mg
Metamizole	500 mg

3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Cattle (adult), horses and dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Horses: **i.v.** only

Cattle, dogs: **i.v.** or **i.m.**

Horses: 5 ml per 100 kg body weight
Adult Cattle: 5 ml per 100 kg body weight
Dogs: 0.1 ml per kg body weight
Due to risk of local reaction, do not use the **i.m.** route in horses.

7. WITHDRAWAL PERIODS

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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf-life after first opening the immediate packaging: 28 days

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Avoid introduction of contamination during use. Should any apparent growth or discolouration occur, discard the veterinary medicinal product.
Following withdrawal of the first dose, use the veterinary medicinal product within 28 days then discard unused material. Keep the container in the outer carton.

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

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 61700/3072

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (Label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buscopan Compositum Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substances:

Butylscopolamine bromide	4 mg
Metamizole	500 mg

3. TARGET SPECIES

Cattle (adult), horses and dogs.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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.

6. EXPIRY DATE

Exp. {mm/yyyy}

Shelf-life after first opening the immediate packaging: 28 days.

Once opened use by:

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Avoid introduction of contamination during use. Should any apparent growth or discolouration occur, discard the veterinary medicinal product. Following withdrawal of the first dose, use the veterinary medicinal product within 28 days then discard unused material.
Keep the bottle in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Buscopan Compositum Solution for Injection

2. 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. Target species

Cattle (adult), horses and dogs.

4. Indications for use

Actions: Butylscopolamine bromide is a spasmolytic agent with particular activity on the smooth muscle of the digestive and urinary systems. Metamizole is a non-steroidal anti-inflammatory drug of the pyrazolone group and also has analgesic and antipyretic effects.
Horses: As an aid in the control of pain associated with simple colic and as a diagnostic aid in more severe colics.
Horses, cattle 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.

5. Contraindications

Due to a risk of local reactions do not use the intramuscular route in horses.

Do not use in pregnant animals as safety during pregnancy in the target species has not been established.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Do not use in horses suffering from paralytic ileus.

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:
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.

Pregnancy and lactation:
Laboratory studies in rabbit and rat 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.

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.

Overdose:
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.

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

7. Adverse events

Cattle, horses and dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylaxis[1] (severe allergic reaction) 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 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 its local representative using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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

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

9. Advice on correct administration

Use aseptic techniques.

10. 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.
Animals should not be slaughtered for human consumption during treatment.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 □C.
Protect from light.
Keep the bottle in the outer carton.
Avoid introduction of contamination during use. Should any apparent growth or discolouration occur, discard the veterinary medicinal product.
Shelf life after first opening the immediate packaging: 28 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

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 61700/3072

Pack size: One 100 ml bottle in a cardboard box.

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 contact details to report suspected adverse events:

UK(GB): Boehringer Ingelheim Animal Health UK Ltd.
Bracknell, RG12 8YS, UK.
Tel: +44 1344 746957

UK(NI): Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173, 55216 Ingelheim am Rhein, Germany.
Tel: +353 1 291 3985

Manufacturer responsible for batch release:

Labiana Life Sciences
08228 Les Fonts de Terassa
Barcelona, Spain

17. Other information

POM-V

Gavin Hall
Approved: 29 October 2026