Boehringer Ingelheim Animal Health UK Ltd

Telephone: Technical Enquiries: 01344 746957

Website:www.boehringer-ingelheim.co.uk/animal-health/animal-health

Email:vetenquiries@boehringer-ingelheim.com

Buscopan Compositum Solution for Injection

Species: Cattle, Dogs, Horses only

Therapeutic indication:Pharmaceuticals: Anti-inflammatory preparations: Injections: Others, **Pharmaceuticals:** Enteric preparations, **Pharmaceuticals: Neurological preparations:** Others

Active ingredient: Butylscopolamine, Metamizole

Product: Buscopan® Compositum Solution for Injection

Product index: Buscopan Compositum

Cattle - meat:9 days iv, 28 days im

Withdrawal notes: Horse meat and offal: 12 days. Not permitted for use in cows producing milk for human consumption.

Incorporating:

Presentation

A slightly yellow solution for injection. Each ml contains 4 mg butylscopolamine bromide and 500 mg metamizole as active substances plus 5 mg phenol as preservative.

Uses

As an aid in the control of pain associated with simple equine colic and as a diagnostic aid in more severe equine colics.

For the control of diarrhoea in cattle, horses and dogs particularly when pain or abdominal discomfort is present.

For the control of pain associated with urinary obstruction in horses and dogs.

Dosage and administration

Use aseptic techniques

Horses: 5 ml per 100 kg bodyweight by intravenous injection only.

Adult Cattle: 5 ml per 100 kg bodyweight by intravenous or intramuscular injection.

Dogs: 0. 1 ml per kg bodyweight by intravenous or intramuscular injection.

Contra-indications, warnings, etc

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

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.

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 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. Avoid use of the product if you are known to be sensitive to pyrazolones, or are sensitive to aspirin. Wash any splashes from the skin. If accidental self-injection occurs, seek medical advice and show the Doctor the product packaging.

Adverse Reactions

In horses, a slight transient increase in heart rate may be observed due to the parasympatholytic activity of butylscopolaminiumbromide (hyoscine butylbromide). In very rare cases, cardiovascular shock may occur if the intravenous injection is administered too fast. In horses, mild tachycardia may be observed occasionally due to the parasympatholytic activity of hyoscine butylbromide.

In very rare cases, anaphylactic reactions may occur and should be treated symptomatically.

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).

Use during pregnancy

Studies in laboratory animals (rabbit, rat) have not produced any evidence of a teratogenic effect. No information on use during pregnancy in the target species is available and therefore this product should not be used.

Interaction with other medicinal products and other forms of interactions

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.

Withdrawal periods

Animals should not be slaughtered for human consumption during treatment.

Meat and offal:

Horses - 12 days

Cattle - 9 days after intravenous injection, 28 days after intramuscular injection.

Do not use in cows producing milk for human consumption.

Pharmaceutical precautions

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

Shelf life of the unopened vial: 3 years

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

Keep out of the reach and sight of children.

For animal treatment only.

NOAH Compendium

To be supplied only on veterinary prescription. To be used in accordance with the directions of a veterinary surgeon.

Any unused product or waste material should be disposed of in accordance with national requirements.

Legal category

Legal category:POM-V

Packaging quantities

Multidose amber 100ml Type II glass injection bottles with grey bromobutyl rubber stoppers and aluminium overseals.

Further information

Pharmacodynamic properties

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.

Pharmacokinetic properties

The quarternary 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.

Marketing Authorisation Number

Vm 08327/4292

Significant changes

GTIN

GTIN description: Buscopan Compositum Solution for Injection

NOAH Compendium

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