SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buscopan Compositum Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Butylscopolamine bromide	4mg
Metamizole	500mg

Excipients

Phenol (as preservative)	5mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection
A slightly yellow solution

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle (adult), horses and dogs.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

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.

4.4 Special warnings for each target species

None

4.5 Special Precautions for Use

i. Special precautions for use in animals

None

ii. 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.

4.6 Adverse reactions (frequency and seriousness)

In horses, a slight transient increase in heart rate may be observed due to the parasympatholytic activity of butylscopolaminiumbromide (hyoscine butylbromide).

4.7 Use during Pregnancy, lactation or lay

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.

4.8 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.

4.9 Amounts to be administered and administration route

Use aseptic techniques.

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal Periods

Meat and Offal:

Horses - 12 days
Cattle - 9 days after i.v. injection, 28 days after i.m. injection.

Not to be used in cows producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QA03DB04 : antispasmodic in combination with analgesic

5.1 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.

5.2 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tartaric acid
Phenol
Water for injection

6.2 Incompatibilities

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

6.3 Shelf Life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years

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

6.4 Special Precautions for Storage

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

6.5 Nature and Contents of Container

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

6.6 Special Precautions for the Disposal of Unused Veterinary Medicinal Product or Waste Materials derived from the use of such products, if appropriate.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 43877/4003

9. DATE OF FIRST AUTHORISATION

29 February 2016

10. DATE OF REVISION OF THE TEXT

February 2016

Approved: 29/02/2016