SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buscopan 20 mg/ml solution for injection for horses and calves

The name "the product" will be used in the SPC].

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Hyoscine butylbromide (Equivalent to 16.32 mg butylhyoscine)	20 mg

Excipients

Methyl parahydroxybenzoate (E 218)	1.8 mg
Propyl parahydroxybenzoate (E 216)	0.2 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Colourless solution for injection

4. CLINICAL PARTICULARS

4.1 Target species

Horses and calves

4.2 Indications for use, specifying the target species

Horse: [The product] is indicated for antispasmodic treatment in case of equine colic.

Calf: [The product] is indicated for its antispasmodic effect, as an aid to the symptomatic treatment of calf scour. Oral re-hydration and other appropriate therapy must also be administered as required.

4.3 Contraindications

Do not use in horses suffering from paralytic ileus.
Do not use in horses less than 6 weeks of age.

See also section 4.11 Withdrawal periods and section 4.7 for use during pregnancy.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

In case of no clinical response the necessity for surgical intervention should be taken into consideration. See also section 4.11 Withdrawal periods.

4.5 Special precautions for use

Special precautions for use in animals
Horses should be monitored carefully following treatment. If the response to treatment with [the product] is poor, careful re-evaluation of the diagnosis should be made and the possibility of surgical intervention should be considered, as [the product] does not mask symptoms of surgical cases.
In cases of mechanical obstruction of the gut, concomitant therapy with polyionic fluids, laxatives and analgetics should be considered.
In animals with cardiac dysfunction the product should be administered after making a risk/benefit assessment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to hyoscine butylbromide or methyl-, or propyl parahydroxybenzoate should avoid contact with the product. Wear impermeable gloves. In the case of accidental spillage onto the skin or eyes, wash off splashes from skin and eyes with clean running water.

4.6 Adverse reactions (frequency and seriousness)

A slight transient increase in heart rate may be observed due to the parasympatholytic activity of hyoscine butylbromide.

4.7 Use during pregnancy, lactation or lay

The use is not recommended during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

The effects of hyoscine butylbromide may be potentiated by the concomitant use of other anticholinergic drugs. Do not use in combination with other drugs that act on the (para) sympathic system. Concomitant therapy should take in consideration the pharmacokinetic properties of hyoscine butylbromide. Concurrent use of Non-Steroidal-Anti-Inflammatory Drugs (NSAIDS), or other products with analgesic properties may mask signs of clinical conditions requiring further diagnosis and treatment.

4.9 Amounts to be administered and administration route

Horse: [The product] should be administered at a dosage of 0.3 mg hyoscine butylbromide per kg body weight, by a single intravenous injection. This corresponds to 1.5 ml of [the product]/100 kg body weight i.v.

Calf: [The product] should be administered at a dosage of 0.4 mg hyoscine butylbromide per kg body weight, by a single intramuscular injection. This corresponds to 2 ml of [the product]/100 kg body weight i.m.

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

In a tolerance study in horses, using up to 5 –fold the recommended dosage of 0.3 mg/kg, the product caused no severe adverse reactions.
A five-fold overdose occasionally produced signs of a transient, slight decrease in defecation frequency. A ten-fold over dosage in horses produced a transitory absence of pupillary light reflex, a transitory increase of heart rate and lower intestinal motility. Signs of colic due to enteroparalysis appear 6 - 8 hours after administration. Adverse reactions after over dosage should disappear without any further treatment within 6 hours.
Intramuscular injection of the product in calves at up to 3-fold of the recommended dose of 0.4 mg/kg caused no systemic nor local adverse reactions.
In case of overdose parasympatholytic symptomatology may be present.

4.11 Withdrawal period(s)

Horse: Meat and offal: 1 day

Calf: Meat and offal: 2 days

Not permitted for use in lactating animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Hyoscine butylbromide is a quaternary ammonium derivative of scopolamine.

Therapeutic subgroup: Synthetic antispasmodic and anticholinergic agents.

ATCvet code: QA03BB01 butylscopolamine (hyoscine butylbromide).

5.1 Pharmacodynamic properties

Like other belladonna alkaloid derivatives, this compound antagonises the actions of acetylcholine at the muscarinic receptor and also possesses slight additional activity at nicotinic receptors. Its pharmacological profile is qualitatively similar to the principal member of this class, atropine. In contrast to atropine hyoscine butylbromide does not cross the blood-brain barrier and exhibits less impact on the cardiovascular system as well as less inhibition of salivary and lacrimal secretion. In comparison to atropine the duration of effect is shorter and disappears without any antidote. The antispasmodic effect of hyoscine butylbromide results in relaxation of smooth musculature lasting for approximately 20 - 45 minutes. A dose dependent increase in heart rate as well as inhibition of salivation and lacrimation can be observed

5.2 Pharmacokinetic particulars

The quaternary ammonium structure of the active substance prevents penetration into the central nervous system after parenteral administration. The elimination half-life from plasma in the target species is 1 - 2 hours. Hyoscine butylbromide is very rapidly eliminated from the blood. Two hours after the intravenous administration of [the product], serum levels of hyoscine butylbromide fall below the lower limit of detection of 100 ng/ml. After parenteral administration in horses, hyoscine butylbromide is eliminated mainly via urine, mainly as unchanged substance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Methyl parahydroxy benzoate (E 218)
Propyl parahydroxy benzoate (E 216)
Water for injections

6.2 Incompatibilities

None known.

6.3 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

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Colourless injection glass vials (type I) with siliconized and Teflon-faced stoppers made of bromobutyl rubber and crimp-on aluminium caps. Each vial contains 50 ml and is packed into a collapsible carton.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused product or waste materials should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4291

9. DATE OF FIRST AUTHORISATION

02 February 2004

10. DATE OF REVISION OF THE TEXT

November 2018

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

Approved: 22 May 2019