PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Hyoscine butylbromide 20 mg/ ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Horses and calves

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Horse: Meat and offal: 1 day

Calf: Meat and offal: 2 days

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

9. EXPIRY DATE

<EXP {month/year}>
Shelf-life of broached vial: 28 days

10. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

12. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

14. MARKETING AUTHORISATION NUMBER

Vm 08327/4291

15. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Hyoscine butylbromide 20 mg/ ml

3. PACKAGE SIZE

50 ml

4. TARGET SPECIES

Horses and calves

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Horse: Single i.v. injection of 1.5 ml/100 kg b.w.

Calf: Single i.m. injection of 2 ml/100 kg b.w.

Read the package leaflet before use.

6. WITHDRAWAL PERIOD

Horse: Meat and offal: 1 day

Calf: Meat and offal: 2 days

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

7. EXPIRY DATE

<EXP {month/year}>
Shelf-life of broached vial: 28 days

8. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

9. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

10. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

11. MARKETING AUTHORISATION NUMBER

Vm 08327/4291

12. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder	Manufacturer for batch release
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK	Boehringer Ingelheim Vetmedica GmbH Binger Strasse 173 55218 Ingelheim am Rhein Germany

2. 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].

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Hyoscine butylbromide 20 mg

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

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

Do not use in horses suffering from paralytic ileus.
Do not use in horses less than 6 weeks of age.
See also section “Withdrawal periods” and section “Special warnings” for use during pregnancy.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

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

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses and calves

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

See section 8.

10. WITHDRAWAL PERIOD

Horse: Meat and offal: 1 day

Calf: Meat and offal: 2 days

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

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

Do not use after the expiry date (EXP) stated on the carton and vial.

Shelf life after first opening the container: 28 days

12. SPECIAL WARNING(S)

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

The use is not recommended during pregnancy.

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.

Interactions
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.

Overdose
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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

to be completed by the Operative Unit after renewal

15. OTHER INFORMATION

50 ml injection vial.

Approved: 22 May 2019