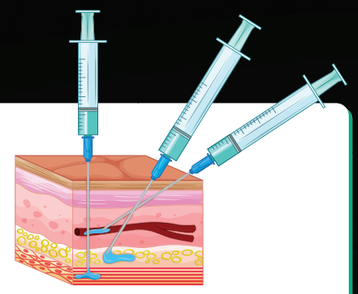
Bromoscol®

Solution for Injection



Route of Administration and Dosage

Horse
- 100 kg /5 ml,
- Intravenous (IV),
- Once a day

Adult Cattle
- 100 kg / 5 ml,
- Intravenous (IV) or intramuscular (IM),
- Twice a day for 3 days

Dog
- 1 kg / 0,1 ml,
- Intravenous (IV), intramuscular (IM) or subcutaneous (SC)
- Once a day,
- If necessary, dose can be repeated after 24 hours.

Withdrawal period:

- Cattle raised for meat should not be sent to slaughter during the treatment and following
  - 18 days from intravenous administration,
  - 28 days from intramuscular administration.
- It is not used in dairy cattle during the lactation.

Shelf Life: **36** months

Pack Size : 100 ml

COMPOSITION: Bromoscol Solution for Injection is a colourless or light yellow coloured, sterile solution and each ml contains 4 mg butylscopolamine bromide (equivalent to 3.27 mg butylscopolamine), 500 mg metamizole sodium monohydrate (equivalent to 443.10 metamizole) as active substances and 5 mg phenol for antimicrobial preservative purposes and 2.5 mg sodium metabisulfite for antioxidant purposes as excipients. PHARMACOLOGICAL PROPERTIES:Pharmacodynamic properties Butylscopolamine bromide (hyoscine butylbromide), a parasympatholytic drug, antagonizes the muscarinic effects of acetylcholine by competitively inhibiting acetylcholine at parasympathetic nerve endings. Its activity on nicotinic receptors reveals only at high (toxic) doses. It inhibits the contraction of smooth muscles of the gastrointestinal tract, urinary and biliary excretory organs. Due to its quaternary ammonium structure, it cannot cross the blood-brain barrier and therefore does not produce the central nervous effects of atropine. Metamizole sodium belongs to the group of pyrazolone derivatives and is used as an analgesic, antipyretic and spasmolytic agent. While it has a central analgesic and antipyretic effect, its anti-inflammatory effect is weaker. It inhibits prostaglandin synthesis by blocking cyclooxygenase. Its analgesic and antipyretic effects are due to inhibition of prostaglandin E2 synthesis. Metamizole sodium has a spasmolytic effect on smooth muscle organs, while also antagonizing the effects of bradykinin and histamine. Pharmacokinetic properties The quaternary ammonium nature of butylscopolamine bromide provides poor absorption after oral administration and prevents the central nervous system penetration after parenteral administration. It has a plasma protein binding of 17-24% and plasma elimination half-life of 2-3 hours. After parenteral administration, approximately 54% is excreted in the urine, mostly unchanged. After oral administration, only about 1% is excreted in the urine. After intravenous administration its effect starts immediately and after intramuscular administration it acts after 20-30 minutes. According to the route of administration and clinical signs, spasmolytic effect continues approximately for 4-6 hours. Metamizole sodium is rapidly absorbed with an absolute bioavailability of almost 100%. Its primary metabolite in plasma and urine is the pharmacologically active 4-methyl-aminoantipyrine (MAA) with a plasma half-life of approximately 6 hours. Other metabolites are found in smaller amounts. Metabolites bind to plasma proteins (at varying rates) and MAA has a plasma protein binding of 56%. Elimination is mainly renal, with 50-70% of the dose being eliminated in the urine, depending on the species and in lactating animals it is also eliminated via milk. AREA OF USE/INDICATIONS: Bromoscol Solution for Injection is used in cattle (adult), horse and dogs. It is used for the control of pain associated with simple equine colic and as a diagnostic aid for 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. ROUTE OF ADMINISTRATION AND DOSAGE: Horse: 5 ml/100 kg body weight by only intravenous route as a single dose. Adult Cattle: 5 ml/100 kg body weight by intravenous or intramuscular routes, twice a day for 3 days.Dog: 0.1 ml/kg body weight by intravenous, intramuscular or subcutaneous routes as a single dose a day. If necessary, dose can be repeated after 24 hours. SPECIAL CLINICAL INFORMATION AND WARNING FOR TARGET SPECIES: In case of intravenous administration of solutions containing metamizole the injection should be slow due to anaphylactic shock risk. To prevent the problems to be caused by doping tests in racing horses, consult a veterinarian about use before and after the race. Tissue irritation may cause in subcutaneous administration. Do not use in horses with paralytic ileus. Due to the presence of metamizole may cause water and salt retention in the kidneys it is not recommended to use in animals with kidney, heart, liver diseases and high blood pressure. Do not use in horses younger than six weeks old. Do not use in target species with gastrointestinal ulceration, chronic gastrointestinal disorders, mechanic obstruction of gastrointestinal system, paralytic ileus, hematopoiesis, coagulopathies, kidney failure, tachyarrhythmia, glaucoma and prostate adenoma. Use during pregnancy and lactation. 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. Metamizole metabolites may pass to the milk by passing the placenta barrier. It is not used during the lactation in dairy cattle raised for human consumption. ADVERSE / SIDE EFFECTS: A slight transient increase in heart rate may be observed in horses due to the parasympatholytic activity of butylscopolamine bromide (hyoscine butylbromide). Anaphylactic reactions may occur very rarely and the treatment should be symptomatic. In case of very fast injection cardiogenic shock may occur very rarely. Concurrent administration of neuroleptics specially phenothiazine derivatives may lead to severe hypothermia. Tissue irritation may occur during subcutaneous administration. DRUG INTERACTIONS: Concurrent use of other anticholinergic or analgesic drugs may strengthen the effects of metamizole and/or butylscopolamine bromide. Together use of drugs such as barbiturates, phenylbutazone may decrease the action time of metamizole. Gastrointestinal hemorrhage may occur when used together with glucocorticoids. It weakens the diuretic effect of furosemide. Together use with other weak analgesics increase the effect and side effects of metamizole. Anticholinergic effect of quinidine and antihistaminics and also tachycardia effects of β-sympathomimetics may increase with this product. Phenobarbital and other barbiturates may fasten the elimination/metabolization of metamizole. SYMPTOMS, PRECAUTIONS AND ANTIDOTE IN OVERDOSE: The acute toxicity of both active substances is very low. In studies with rats the symptoms were non-specific and included ataxia, mydriasis, tachycardia, prostration, convulsions, coma and respiratory signs. Antidote of butylscopolamine is physostigmine. There is no specific antidote for metamizole sodium, symptomatic treatment should be initiated in case of overdosage. Anticholinergic symptoms may occur such as urine retention, lack of water, tachycardia, inhibition of gastrointestinal motility and transient visual disorder. If necessary, parasympathomimetic drugs may be administered. Excessive doses in small breed dogs may cause attacks because of the phenol in the composition. WITHDRAWAL PERIOD: The cattle raised for meat should not be sent to slaughter during the treatment and following 18 days from intravenous administration and 28 days from intramuscular administration. It is not used in dairy animals producing milk for human consumption during the lactation. 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 substances or any of the excipients. Do not use in horses with paralytic ileus. Due to the presence of metamizole may cause water and salt retention in the kidneys it is not recommended to use in animals with kidney, heart, liver diseases and high blood pressure. Do not use in horse younger than six weeks old. Do not use in target species with gastrointestinal ulceration, chronic gastrointestinal disorders, mechanic obstruction of gastrointestinal system, paralytic ileus, hematopoiesis, coagulopathies, kidney failure, tachyarrhythmia, glaucoma and prostate adenoma. GENERAL WARNINGS: Consult a veterinary physician before use and in case of unexpected effect. Keep out of reach of children. SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VETERINARY MEDICINAL PRODUCT: Avoid self-injection with the product. In case of accidental self-injection seek medical advice and show the package insert to the doctor. In 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 sensitive to aspirin. In case of splashing to the skin wash and clean. Accidental self-injection may cause negative effects on cardiac and circulatory, STORAGE CONDITIONS AND SHELF LIFE: Shelf life is 36 months when stored at room temperature below 25°C without refrigeration and/or freezing and in the original package. After opening, the shelf life is 28 days when stored at room temperature below 25°C without refrigeration and/or freezing. The stopper can be perforated for maximum 40 times. DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES: Any unused veterinary medicinal product or any waste material remaining from such a product should be disposed of as per the requirements of local laws. NATURE AND COMPOSITION OF IMMEDIATE PACKAGING: It is presented in 100 ml amber coloured Type II glass vials covered with red coloured 20 mm chlorobutyl rubber stopper and white flip-off cap in the cardboard box. TERMS OF SALE: Sold only in veterinary clinics and pharmacies by veterinary prescription. MARKETING AUTHORIZATION DATE AND NO. 26.05.2021 – 029/0094 NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER: DEVA Holding A.Ş. Halkalı Merkez Mahallesi Basın Ekspres Cad. No:1 Küçükçekmece/İstanbul/TÜRKİYE Phone: +90 212 692 92 92 Fax: +90 212 697 34 89 e-mail: vetas@vetas.com.tr NAME AND ADDRESS OF THE MANUFACTURING SITE:DEVA Holding A.Ş. Çerkezköy Organize Sanayi Bölgesi, Atatürk Cad. Karaağaç Mah. No.32 Kapaklı/Tekirdağ/TÜRKİYE Phone: +90 282 735 20 00 Fax: +90 282 758 30 59

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Please contact our company for more information. **DEVA HOLDİNG A.Ş.** Halkalı Merkez Mah. Basın Ekspres Cad. No:1 34303 Küçükçekmece / İSTANBUL Tel: 0212 692 92 92 Faks: 0212 697 34 89 • www.vetas.com.tr

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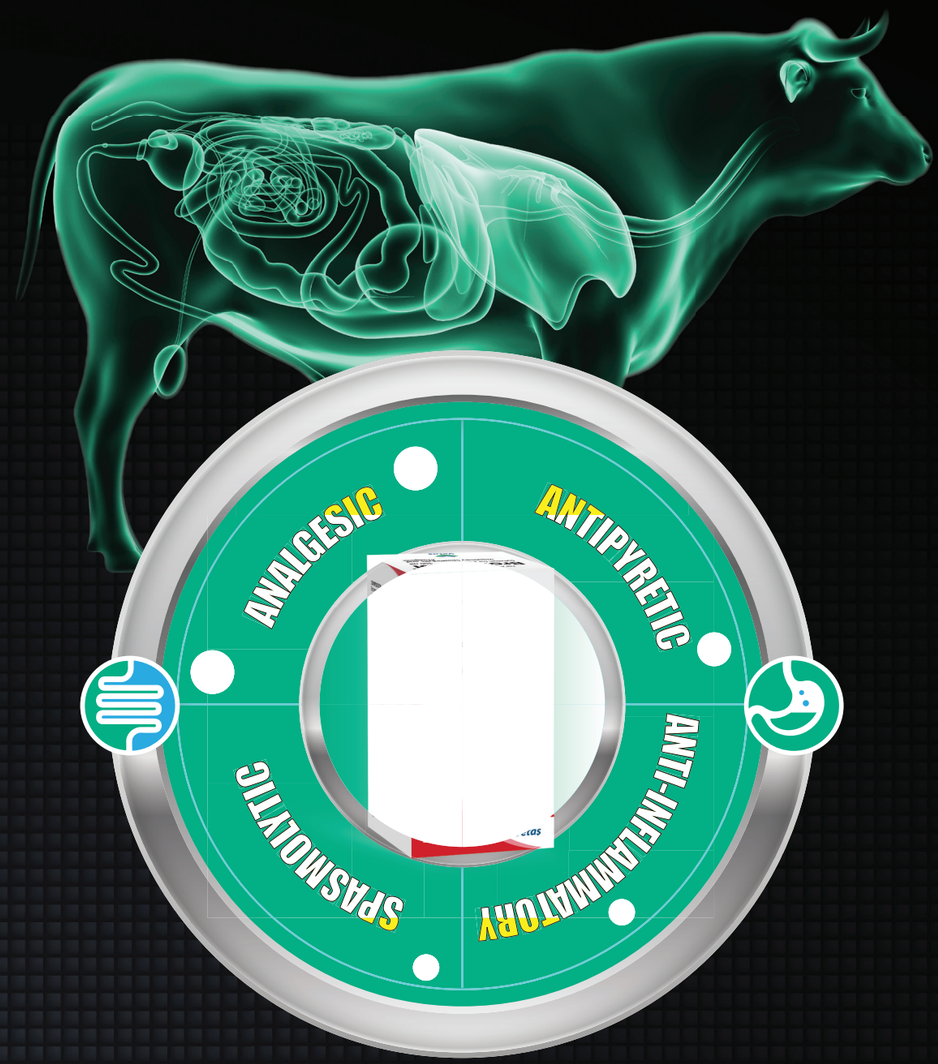


FOR ACHES AND PAINS...

Vetaş

Bromoscol®

Solution for Injection

Butylscopolamine + Metamizole

Analgesic › Antipyretic › Anti-inflammatory › Spasmolytic

Butylscopolamine is an:

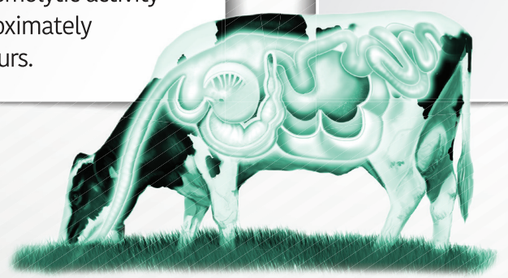
Antispasmodic, Antimuscarinic, Anticholinergic drug.

- It blockades parasympathetic receptor. Thus, it efficiently inhibits the gastrointestinal system secretions and motility.
- It inhibits the contraction of smooth muscles of the gastrointestinal system, urinary system, uterus and biliary excretory organs.
- It is absorbed very rapidly.
- After intravenous administration its effect starts immediately and after intramuscular administration it acts after 20-30 minutes.
- According to the route of administration and clinical signs, spasmolytic activity continues approximately for 4-6 hours.

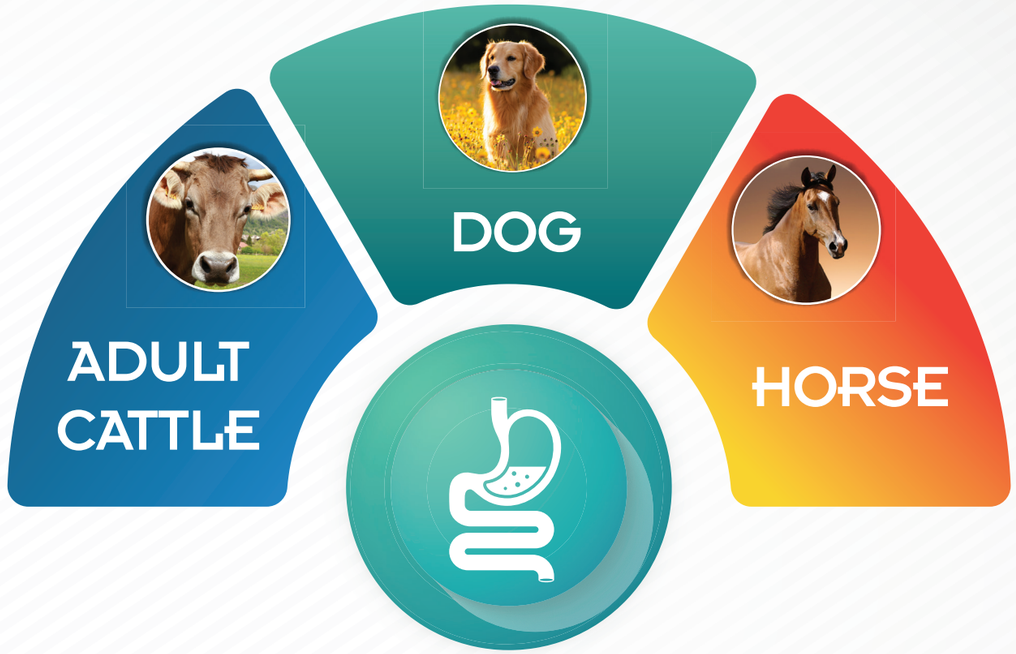
Metamizole:

Analgesic, Antipyretic, Spasmolytic and **Anti-inflammatory** drug.

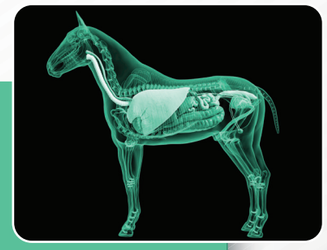
- While it has a strong analgesic and antipyretic effect, its anti-inflammatory effect is weaker.
- It has a spasmolytic effect on smooth muscle organs.
- It also antagonizes the effects of histamine.
- It is absorbed rapidly.
- Plasma half-life is approximately 6 hours.
- Bioavaliability is approximately %100.



TARGET SPECIES



AREA OF USE



Bromoscol Solution for Injection,

Horses,
For the control of pain associated with simple equine colic and as a diagnostic aid,

Cattle, horses and dogs,
For the control of diarrhea in particularly when pain or abdominal discomfort is present,

Horses and dogs,
For the control of pain associated with urinary obstruction.