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Spasmalgan® compositum

Solution for injection for horses, cattle, pigs and dogs

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT
Veyx-Pharma GmbH
Soehreweg 6
34639 Schwarzenborn
Germany

NAME OF THE VETERINARY MEDICINAL PRODUCT
Spasmalgan® compositum, 500 mg/ml + 4 mg/ml
Solution for injection for horses, cattle, pigs and dogs
Metamizole sodium monohydrate, hyoscine butylbromide

STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS
Spasmalgan® compositum is a clear yellow solution for injection containing:

Active substances:	
Metamizole sodium monohydrate (equivalent to 443.00 mg/ml metamizole)	500.00 mg/ml
Hyoscine butylbromide (equivalent to 2.76 mg/ml hyoscine)	4.00 mg/ml
Excipients:	
Benzyl alcohol (E1519)	10.00 mg/ml

INDICATIONS
Treatment of spasms or sustained increased tonus of smooth muscles of the gastrointestinal tract or of the urine and bile excretory organs associated with pain.

Horses:
Spasmodic colics

Cattle/Calves, pigs, dogs:
As supportive therapy for acute diarrhoea

CONTRAINDICATIONS
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Due to the content of metamizole sodium, do not use in case of:
- disorders of the haematopoietic system
- gastrointestinal ulcers
- chronic gastro-intestinal disorders
- renal insufficiency
- coagulopathies

Due to the content of hyoscine butylbromide do not use in case of:
- mechanic stenoses in the gastro-intestinal system
- tachyarrhythmia
- glaucoma
- prostate adenoma

ADVERSE REACTIONS
In very rare cases, anaphylactic reactions and cardiovascular shock may occur.
In dogs painful reactions can occur immediately after injection, which abate rapidly and have no negative impact on the expected therapeutic benefit.
In horses and cattle, a slight increase in heart rate may be observed occasionally due to the parasympatholytic activity of hyoscine butylbromide.

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 1000 animals treated)
- Rare (more than 1 but less than 10 animals in 10000 animals treated)
- Very rare (less than 1 animal in 10000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

TARGET SPECIES
Horses, cattle, pigs and dogs

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
Administration route:

Horses, cattle:	slow intravenous use
Pigs:	intramuscular use
Dogs:	intramuscular and slow intravenous use

Due to the risk of anaphylactic shock metamizole-containing solutions should be administered slowly when given intravenously.

Dosage instructions:

Horses:	25 mg metamizole sodium monohydrate/kg BW and 0.2 mg hyoscine butylbromide/kg BW (equivalent to 2.5 ml of Spasmalgan® compositum per 50 kg BW)
Cattle:	40 mg metamizole sodium monohydrate/kg BW and 0.32 mg hyoscine butylbromide/kg BW (equivalent to 4 ml of Spasmalgan® compositum per 50 kg BW)
Calves:	50 mg metamizole sodium monohydrate/kg BW and 0.4 mg hyoscine butylbromide/kg BW (equivalent to 1 ml of Spasmalgan® compositum per 10 kg BW)
Pigs:	50 mg metamizole sodium monohydrate/kg BW and 0.4 mg hyoscine butylbromide/kg BW (equivalent 1 ml of Spasmalgan® compositum per 10 kg BW)
Dogs:	50 mg metamizole sodium monohydrate/kg BW and 0.4 mg hyoscine butylbromide/kg BW (equivalent to 0.1 ml of Spasmalgan® compositum per kg BW)

Treatment frequency:

Cattle and Calves:	up to twice daily for three days
Horses and pigs:	single injection
Dogs:	single injection that can be repeated after 24 hours if necessary

ADVICE ON CORRECT ADMINISTRATION
The stopper must not be punctured more than 100 times. The user should select the most appropriate vial size according to the target species to be treated.

WITHDRAWAL PERIODS

Horses, cattle (i.v.):	Meat and offal	12 days
Cattle (i.v.):	Milk	96 hours
Pigs (i.m.):	Meat and offal	15 days

Not authorised for use in horses producing milk for human consumption.

SPECIAL STORAGE PRECAUTIONS
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days

When the container is broached (opened) for the first time, using the in-use shelflife which is specified on this package insert, the date on which any product remaining in the vial should be discarded should be worked out. This discard date should be written in the space provided on the label.

Do not store above 25 °C.
Keep the vial in the outer carton in order to protect from light.
Do not freeze.

SPECIAL WARNING(S)
Special warnings for each target species:
None.

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 veterinary medicinal product to animals:
In a very small number of people metamizole can cause reversible, but potentially serious agranulocytosis and other reactions such as skin allergy. Hyoscine butylbromide can potentially effect gastrointestinal tract motility and cause tachycardia. Take care to avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
People with known hypersensitivity to metamizole, hyoscine butylbromide or benzyl alcohol should avoid contact with the veterinary medicinal product. Avoid use of the product if you are known to be sensitive to pyrazolones, or are sensitive to acetylsalicylic acid.
This veterinary medicinal product can cause skin and eye irritation. Avoid contact with skin and eyes. In the case of contact with skin, wash with soap and water immediately. If the product comes into contact with the eyes, rinse the eyes immediately with plenty of water. If skin or eye irritation persists, seek medical advice. Fetotoxicity was sporadically observed following metamizole intake in the third trimester of pregnancy in humans. Furthermore, metamizole intake by breast-feeding women might be harmful for their babies. Therefore, pregnant women in the third trimester and breast-feeding women should not administer this veterinary medicinal product.

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. However, hyoscine butylbromide may have effects on smooth muscle of the birth canal. Metabolites of metamizole can cross the placental barrier and penetrate into milk. Therefore, this product should be used in pregnant and lactating animals only according to the benefit risk assessment by the responsible veterinarian.

Interactions with other medicinal products and other forms of interaction:
The effects of metamizole and/or hyoscine butylbromide may be potentiated by concurrent use of other anticholinergic or analgesic substances.
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 furo-semide is attenuated. Co-administration of other weak analgesics increases the effects and side-effects of metamizole.
The anticholinergic action of quinidine and antihistaminics as well as the tachycardic effects of β-sympathomimetics may be enhanced by this veterinary medicinal product.

Overdose (symptoms, emergency procedures, antidotes):
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, unconsciousness and respiratory signs.

In case of overdosage treatment should be discontinued. Physostigmine is recommended as an antidote to hyoscine butylbromide. A specific antidote for metamizole sodium is not available. Therefore, symptomatic treatment should be initiated in case of overdosage.

Due to the parasympatholytic activity of hyoscine butylbromide a slight increase in the heart rate was observed in some cases in horses and cattle following administration of the double therapeutic dose.

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

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY
Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment

To be supplied only on medical prescription

OTHER INFORMATION
Package size:
1 vial of 100 ml in a cardboard box