1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sympagesic 500 mg/ml + 4 mg/ml solution for injection for horses, cattle, pigs and dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Metamizole (as metamizole sodium monohydrate) 443 mg
equivalent to 500.0 mg metamizole sodium monohydrate

Hyoscine (as hyoscine butylbromide) 2.76 mg
equivalent to 4.0 mg hyoscine butylbromide

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Phenol	5.00 mg
Tartaric acid (E 334)	
Water for injections	

Clear, yellowish solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses, cattle, pigs and dogs.

3.2 Indications for use for each target species

Horses, cattle, pigs, dogs:
Treatment of smooth muscle spasms and pain associated with underlying disorders of the gastro-intestinal tract, urogenital system and bile excretory organs.

Horses only:
Spasmodic colics.

Cattle, pigs, dogs:
Supportive therapy for acute diarrhoea and gastroenteritis.

3.3 Contraindications

Do not use in cases of:
- gastro-intestinal ulceration
- chronic gastro-intestinal disorders
- mechanic obstruction in the gastro-intestinal system
- paralytic ileus
- disorders of the haematopoietic system
- coagulopathies
- renal insufficiency

- tachyarrhythmia
- glaucoma
- prostate adenoma.

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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. 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.
Avoid skin and eye contact. People with known hypersensitivity to metamizole or hyoscine butylbromide should avoid contact with the veterinary medicinal product. Avoid use of the veterinary medicinal product if you are known to be sensitive to pyrazolones or are sensitive to acetylsalicylic acid.
Wash splashes from skin and eyes immediately.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reaction[a] Circulatory shock[b]
Undetermined frequency (cannot be estimated from the available data)	Tachycardia[c]

[a] Should be treated symptomatically.
[b] In case of too fast intravenous injection.
[c] Mild. Due to the parasympatholytic activity of hyoscine butylbromide.

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reaction[a] Circulatory shock[b] Injection site pain[c]

[a] Should be treated symptomatically.
[b] In case of too fast intravenous injection.
[c] Immediate. Abates rapidly and does not have a negative impact on the expected therapeutic benefit.

Cattle, pigs:

Very rare	Anaphylactic-type reaction[a]

(<1 animal / 10,000 animals treated, including isolated reports):	Circulatory shock[b]

[a] Should be treated symptomatically.
[b] In case of too fast intravenous injection.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation in the target species.

Pregnancy and lactation:
Laboratory studies in rabbits and rats have not produced any evidence of teratogenic effects.
Metabolites of metamizole cross the placental barrier and penetrate into milk.
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction 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 furosemide 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.

3.9 Administration routes and dosage

Horse: slow intravenous use.
Pig: slow intravenous use or intramuscular use.
Single injection of 20 - 25 mg metamizole sodium monohydrate/kg body weight and 0.16 - 0.2 mg hyoscine butylbromide/kg body weight i.e. once 4 - 5 ml per 100 kg.
For pigs, maximum injection volume is 5 ml per injection site.

Cattle: slow intravenous use or intramuscular use.
Up to twice daily for three days, 20 - 25 mg metamizole sodium monohydrate/kg body weight and 0.16 - 0.2 mg hyoscine butylbromide/kg body weight i.e. 4 - 5 ml per 100 kg twice daily up to three days.

Dog: slow intravenous use or intramuscular use.
Single injection of 50 mg metamizole sodium monohydrate/kg body weight and 0.4 mg hyoscine butylbromide/kg body weight i.e. once 0.5 ml per 5 kg. Treatment can be repeated after 24 hours if necessary.

The stopper must not be punctured more than 25 times.

To ensure a correct dosage, body weight should be determined as accurately as possible.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdosage, the symptoms of atropine intoxication can be observed (dryness of the mucous membranes, mydriasis, tachycardia), due to the parasympatholytic activity of hyoscine butylbromide. In case of overdosage, treatment should be discontinued. Parasympaticomimetics, such as physostigmine and neostigmine, are recommended as antidotes to hyoscine butylbromide. A specific antidote for metamizole sodium is not available. Therefore, symptomatic treatment should be initiated in case of overdosage.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable

3.12 Withdrawal periods

Cattle
Meat and offal: 18 days following intravenous administration.
Meat and offal: 28 days following intramuscular administration.
Not authorised for use in animals producing milk for human consumption.
Do not use in pregnant animals which are intended to produce milk for human consumption within 2 months of expected parturition.

Horses
Meat and offal: 15 days.
Not authorised for use in animals producing milk for human consumption.
Do not use in pregnant animals which are intended to produce milk for human consumption within 2 months of expected parturition.

Pigs
Meat and offal: 15 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :
QA03DB04

4.2 Pharmacodynamics
Hyoscine butylbromide (butylscopolamine bromide) is a quaternary ammonium compound of hyoscine and is an antispasmodic agent which relaxes smooth muscle of the organs of the abdominal and pelvic cavities. It is believed to act predominantly on the intramural parasympathetic ganglia of these organs. Hyoscine antagonises the actions of acetylcholine mediated through the muscarinic receptor. It also has some antagonist effect at nicotinic receptors. Due to its chemical structures as a quaternary ammonium derivative, hyoscine is not expected to enter the central nervous system, therefore, does not produce secondary anticholinergic effects in the central nervous system.

Metamizole belongs to the group of pyrazolone derivatives and is used as an analgesic, antipyretic and spasmolytic agent. It has significant central analgesic and antipyretic, but only low anti-inflammatory effect (weak analgesics). Metamizole inhibits the synthesis of prostaglandins by blocking the cyclooxygenase. The analgesic and antipyretic effect is mainly due to inhibition of prostaglandin E_2 synthesis. In addition, metamizole has a spasmolytic effect on smooth muscle organs. Metamizole sodium further antagonises the effects of bradykinin and histamine.

4.3 Pharmacokinetics

Hyoscine butylbromide is 17 – 24% bound to plasma proteins. The elimination half-life is 2 – 3 hours. Hyoscine butylbromide is mainly eliminated unchanged in urine (approx. 54%).

Metamizole sodium is rapidly metabolised by hydrolysis into the primary pharmacologically active metabolite 4 methyl-aminoantipyrine (MAA). Other metabolites (4 acetyl aminoantipyrine (AAA), 4 formyl aminoantipyrine (FAA) and aminoantipyrine (AA)) are present in smaller quantities. Plasma protein binding of the metabolites is as follows: MAA: 56%, AA: 40%, FAA: 15%, AAA 14%. The elimination half-life of MAA is 6 hours. Metamizole is primarily eliminated renally.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

After first opening the immediate packaging do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Cardboard box with amber glass vial (type II) with bromobutyl rubber stopper and aluminium cap.
Pack sizes: 100 ml, 5 x 100 ml.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V

7. MARKETING AUTHORISATION NUMBER(S)

VPA22622/033/001

8. DATE OF FIRST AUTHORISATION

26/06/2019

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

03/07/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).