ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER AND THE IMMEDIATE PACKAGE

Outer carton for 100 ml vials and outer carton of multi-packs
Glass vials of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sympagesic 500 mg/ml + 4 mg/ml solution for injection for horses, cattle, pigs and dogs
Metamizole sodium monohydrate + hyoscine butylbromide

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains

Metamizole sodium monohydrate 500 mg
Hyoscine butylbromide 4 mg

3. PHARMACEUTICAL FORM

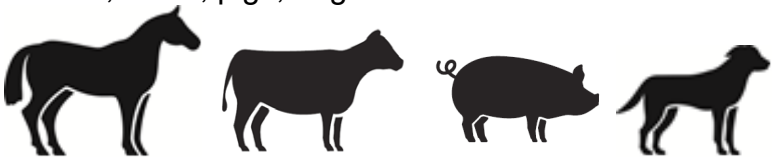
Solution for injection

4. PACKAGE SIZE

100 ml
5 x 100 ml

5. TARGET SPECIES

Horses, cattle, pigs, dogs



6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous or intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the bottle: 28 days
Once broached use by…

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.

13. 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.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 50406/4008

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

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

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

Marketing authorisation holder:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Ireland only:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer responsible for batch release:
Genera Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sympagesic 500 mg/ml + 4 mg/ml solution for injection for horses, cattle, pigs and dogs
metamizole sodium monohydrate
hyoscine butylbromide

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each ml contains:

Active substances:

Metamizole sodium monohydrate (equivalent to 443 mg metamizole)	500.0 mg
Hyoscine butylbromide (equivalent to 2.76 mg hyoscine)	4.0 mg

Excipients:

Phenol	5.0 mg

Clear, yellowish solution.

4. INDICATIONS

Horses, cattle, pigs, dogs: treatment of smooth muscle spasms and pain 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.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

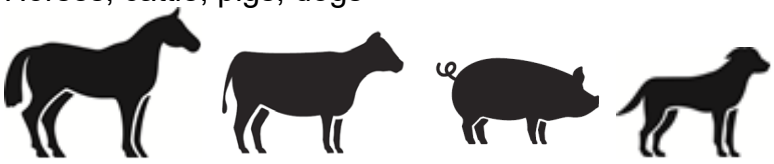
In very rare cases, anaphylactic reactions may occur and should be treated symptomatically.
In very rare cases, cardiovascular shock may occur if the intravenous injection is administered too fast.
In horses, mild tachycardia may be observed occasionally due to the parasympatholytic activity of hyoscine butylbromide.
In dogs painful reactions at the injection site can occur immediately after injection, which abate rapidly and have no negative impact on the expected therapeutic benefit.

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 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 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.

7. TARGET SPECIES

Horses, cattle, pigs, dogs



8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

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.
In 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: intravenous (slow) 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.

9. ADVICE ON CORRECT ADMINISTRATION

The stopper must not be punctured more than 25 times.

10. 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
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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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

After first opening the immediate packaging do not store above 25 °C.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the bottle: 28 days

12. SPECIAL WARNINGS

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. 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 product if you are known to be sensitive to pyrazolones, or are sensitive to acetylsalicylic acid.
Wash splashes from skin and eyes immediately.

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. Metabolites of metamizole cross the placental barrier and penetrate into milk. Therefore this product should be used only according to the benefit-risk assessment by the responsible veterinarian.

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.

Overdose (symptoms, emergency procedures, 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.

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

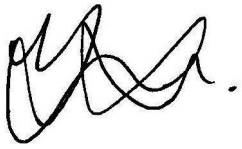
March 2020

15. OTHER INFORMATION

Packaging:
Cardboard box with one amber glass vial (type II) containing 100 ml with a bromobutyl rubber stopper and aluminium cap.

Pack sizes:
Box with 1 vial of 100 ml
Multi-pack with 5 boxes each containing 1 vial of 100 mL

Not all pack sizes may be marketed.



Approved: 18 August 2023