[Version 8.1,01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rivalgin 500 mg/ml solution for injection
(BE, BG, CZ, ES, HR, HU, IT, LT, PT)

Rivalgin vet. 500 mg/ml solution for injection
(DK, IS, NO)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:
Active substance:
Metamizole sodium monohydrate 500 mg
(equivalent to metamizole 443.1 mg)

Excipients:
Benzyl alcohol (E1519) 30 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, yellowish solution, practically free of particulate matters.

4. CLINICAL PARTICULARS

4.1 Target species

Horses, cattle, pigs, dogs.

4.2 Indications for use, specifying the target species

Diseases of horses, cattle, pigs and dogs where a positive effect of the central analgesic, spasmolytic, antipyretic or low anti-inflammatory effects of the product can be expected, such as:

General pain relief to suppress nervousness and defensive reactions caused by pain.
Attenuation of pain in colic conditions of varying origins or spastic states of the internal organs in horses and cattle.
Occlusion of the oesophagus with foreign bodies in horses, cattle and pigs.
Feverish illnesses such as severe mastitis, MMA syndrome, swine flu.
Lumbago, tetanus (in combination with tetanus antiserum).
Acute and chronic arthritis, rheumatic states of muscles and joints, nerve inflammation, neuralgia, tendovaginitis.

4.3 Contraindications

Do not use in cats.
The product should not be used in animals with haematopoietic disorders.
Do not administer subcutaneously due to possible local irritation.
Do not use in cases of hypersensitivity to the active substance, or to any of the excipients.
Do not use in cases of heart, hepatic or renal failure or gastro-intestinal ulceration.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Due to the risk of anaphylactic shock, metamizole-containing solutions should be administered slowly when given intravenously.
Avoid concomitant administration with potentially nephrotoxic drugs.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to metamizole should avoid contact with the veterinary medicinal product. Avoid use of the product if you are known to be sensitive to pyrazolones, or to acetylsalicylic acid. Pregnant and breast-feeding women should handle this product with caution.

This product may be irritant to skin and eyes. Avoid contact with the skin and eyes. Wash any splashes from skin and eyes immediately with plenty of water. Seek medical advice if irritation persists.

Metamizole can cause reversible, but potentially serious agranulocytosis. 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.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy and lactation

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Phenobarbital and other barbiturates as well as glutethimide or phenylbutazone can accelerate metamizole excretion due to hepatic microsomal enzyme induction.
Concomitant use of phenothiazine derivatives may lead to severe hypothermia.

4.9 Amounts to be administered and administration route

Horses: Slow intravenous use.
Cattle, pigs, dogs: Slow intravenous use (in acute conditions) or deep intramuscular use.

Horses: 20-50 mg of metamizole sodium monohydrate/kg BW (4-10 ml of the product/100 kg BW)
Cattle: 20-40 mg of metamizole sodium monohydrate/kg BW (4-8 ml of the product/100 kg BW)
Pigs: 15-50 mg of metamizole sodium monohydrate/kg BW (3-10 ml of the product/100 kg BW)
Dogs: 20-50 mg of metamizole sodium monohydrate/kg BW (0.4-1 ml of the product/10 kg BW)

When used intramuscularly in cattle the maximum volume applied to one site should not exceed 29 ml. In pigs, when administering volumes larger than 20 ml these should be divided between at least two injection sites.

The rubber stopper can be punctured a maximum of 25 times.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Effects on the central nervous system such as sedation and convulsions have been reported in all target species at doses from 1,000 to 4,000 mg/kg of bodyweight.
In case of overdose, follow the standard procedures and, if necessary, administer intravenous diazepam to control the seizures.

4.11 Withdrawal period(s)

Horses: Meat and offal (intravenous application): 5 days
Cattle: Meat and offal: 12 days
Milk: 48 hours
Pigs: Meat and offal: 12 days

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: other analgesics and antipyretics.
ATC vet code: QN02BB02.

5.1 Pharmacodynamic properties

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 effects. 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.

5.2 Pharmacokinetic particulars

Metamizole is rapidly absorbed after administration and reaches maximum blood levels within 1-2 hours.
After 2 hours it is evenly distributed in tissues and 1-2 hours thereafter the concentration decreases to 1-3 % of maximum levels. It is metabolised by hydrolysis into various metabolites of which the most important pharmacologically active are methylaminoantipyrine (MAA) and aminoantipyrine (AA). Most of metamizole and its metabolites are excreted via the kidneys (85 %), and about 15 % in the faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.

Shelf life after first opening the immediate packaging: 28 days.

6.4. Special precautions for storage

Do not refrigerate or freeze.

6.5 Nature and composition of immediate packaging

Clear glass vial type II with bromobutyl rubber stopper and aluminium pull off or aluminium/plastic flip off cap.

Package size: 1 x 100 ml, 5 x 100 ml
Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE