

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novacoc forte - Solution for infusion for animals

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml contain:

Active substances:

Metamizole sodium	4.00 g
Caffeine	0.35 g
Calcium gluconate	10.00 g
Magnesium gluconate	1.00 g
Sodium dihydrogen phosphate dihydrate	0.402 g
Acetylmethionine	4.00 g
Glucose (as monohydrate)	18.182 g

Excipients:

Benzyl alcohol 1.05 g

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion

Clear, yellowish to orange-yellow solution

4. CLINICAL PARTICULARS

4.1 Target species

Horse, cattle, pig

4.2 Indications for use, specifying the target species

For supportive treatment in case of downer cow syndrome as well as in case of pain and febrile diseases caused by infections and intoxications such as coli-mastitis, acute and severe septicaemia, puerperal septicaemia, diarrhoea and pneumonia.

Novacoc forte is recommended in addition to an anti-infective therapy.

4.3 Contraindications

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

Do not use in case of severe liver and kidney damage, blood formation disorders, bronchial asthma, in case of gastro-intestinal ulcers, chronic gastro-intestinal disorders, hypercalcaemia, coagulopathy, cardiac insufficiency and arrhythmia.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Infuse slowly intravenously at body temperature while monitoring heart rate. Discontinue infusion in case of tachycardia and cardiac arrhythmia. Caution in case of suspected heart disease (calcium-shock). Medicinal products containing calcium can cause allergic reactions based on histamine release when the maximum infusion rate is exceeded.

In case of long-term use monitor blood count.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Infusion at a too high rate may result in tachycardia and cardiac arrhythmia.

Especially long-term and high-dose administration of the veterinary medicinal product can promote the occurrence of the following adverse reactions:

Irritation and risk of bleeding of the gastro-intestinal tract, impairment of renal function, blood count changes, leukopenia in horses, bronchospasms in predisposed animals.

4.7 Use during pregnancy, lactation or lay

The use during the late phase of pregnancy requires a strict indication.

Metabolites of metamizole cross the placental barrier and penetrate into milk.

4.8 Interaction with other medicinal products and other forms of interaction

Metamizole may intensify the effect of anticoagulants and attenuate the diuretic effect of furosemide. The combination of metamizole with neuroleptics (especially phenothiazine derivatives) causes severe hypothermia. Simultaneous administration of inducers of liver microsomal enzymes (barbiturates, phenylbutazone) reduces the half-life and therefore the duration of action of metamizole.

Simultaneous administration of glucocorticoids increases the risk of gastro-intestinal bleeding.

Simultaneous administration of other weak analgesics intensifies the effects and adverse effects of metamizole. The effect of cardiac glycosides and adrenergics (etilefrine) is intensified by calcium.

Cardiac arrhythmia may occur with concomitant administration of inhalation narcotics. Magnesium gluconate attenuates the effect of aminoglycosides and tetracyclines and intensifies the neuromuscular-blocking action of aminoglycosides and inhalation narcotics. Caffeine intensifies the effect of cardiac glycosides.

4.9 Amounts to be administered and administration route

Infuse slowly at body temperature.

Cattle/horses: 50 ml/100 kg

Pigs: 4.5 ml/10 kg

Administration for more than three days requires a re-evaluation of indication.

The administration can be repeated once daily, depending on the course of the disease.

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

Undesirable effects are primarily caused by too rapid infusions. They include circulatory collapse, cardiac arrhythmia, dyspnoea, spasms, muscular weakness. In these cases, discontinue the infusion and if necessary start symptomatic treatment.

4.11 Withdrawal period(s)

Meat and offal:

Pig: 3 days

Cattle: 13 days

Horse: 6 days

Milk: 2 ½ days (5 milkings)

Do not use in mares producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Pyrazolones, ATCvet code: QN02BB52

5.1 Pharmacodynamic properties

Novacoc forte is a combination of metamizole and caffeine with organotropic acting co-factors in a glucose solution for the treatment of febrile infectious and invasive diseases associated with severely impaired general body condition, symptoms of intoxication and metabolic disorders in livestock.

Metamizole belongs to the group of pyrazolone derivatives and is used as analgesic, antiphlogistic, antipyretic and spasmolytic.

It belongs to the group of non-steroidal antiphlogistics, which have a pronounced central analgetic and antipyretic, but only a weak antiphlogistic effect (weak analgesics).

Like all weak analgesics or non-steroidal antiphlogistics metamizole inhibits prostaglandin synthesis by blocking cyclooxygenase. The analgetic and antipyretic effect is mainly related to the inhibition of synthesis of prostaglandin E2, which is involved in central as well as peripheral pain perception and transmission. In addition metamizole has a spasmolytic effect on smooth-muscle tissues.

Caffeine has a stimulating effect on the CNS; respiration and motoric activity are stimulated. It also shows anticonvulsive and angiospasmolytic effects. There is a mild digitalis-like cardiac effect and mild dilation of the coronary vessels which result in decreased heart contraction rate and increased cardiac output. The higher perfusion of the glomeruli together with mobilisation of large quantities of tissue-fluid leads to increased diuresis and reduction of oedema.

Calcium is contained as gluconate, which is better tolerated and easily absorbed.

It is involved in many biochemical reactions of the organism, such as blood coagulation, central and peripheral nervous excitability, muscle excitability and -contraction, demaceration, sealing of vessels, as well as it is part of any inflammatory process and allergic reaction. It is the "second messenger" of some hormones and activates a wide array of enzymes. Due to its organotropic effect, calcium also has some calming effect on the CNS and an immediate spasmolytic effect in the various forms of tetany.

Magnesium activates the function of the phosphatase enzymes, which play an important role in the body metabolism and muscle contraction. Magnesium ions are contained as gluconate.

Phosphor stimulates the body metabolism by assimilatory support of the carbohydrate balance, resulting in an increased supply of energy.

Methionine is an essential amino acid and an important part of some proteins in the animal's organism. It contains molecular sulfur and is thus the donor for synthesis of cysteine and thence cystine, two important sulfur containing amino acids.

As a lipotropic factor it is also involved in the synthesis of phosphatide and supports the transport of fatty acids from the liver.

Glucose is the most important source of energy in cell metabolism. In addition to glycolysis for energy supply, glucose is required for the formation of glycogen as storage form of carbohydrates, for upkeep of the blood sugar level and for biosynthesis of important body components.

5.2 Pharmacokinetic particulars

The supplied active ingredients are bound to plasma proteins and metabolized according to their pharmacokinetic features (if necessary, glucose is used up to 99 %, otherwise up to 40% is excreted via urine).

The onset of metamizole effect can be expected after about 10-15 minutes after IV injection. Caffeine, which is a methylxanthine, has a $t_{1/2}$ of 18-22 hours in horses (max. plasma concentration 5 minutes after IV application) and is partially demethylated. Calcium (bound up to 40 %) and magnesium (bound up to 35%) are distributed in the extracellular space. Methionine is metabolised to cysteine in the liver.

Most of the metabolites are excreted via urine. Magnesium is eliminated mainly via faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol, boric acid, sodium hydroxide, water for injections

6.2 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: 2 years

Shelf life after first opening the immediate packaging: 28 days if stored in a refrigerator (2 ° - 8 °C).

6.4. Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).

Keep the glass vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

White glass vial 250 ml, glass type II, Ph. Eur. with bromobutyl rubber stopper type I, Ph. Eur. and aluminium cap.

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

10. DATE OF REVISION OF THE TEXT

April 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Only on veterinary prescription. Available only in pharmacies.