NEVIT FORTE INJECTION

(Novaminsulfon, Etilefrin, Calcium Gluconate, Magnesium Gluconate, Sodium Salicylate, Nicotinamide, Caffeine, Boric Acid)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

NEVIT FORTE INJECTION.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:
Novaminsulfon ……. 40mg
Etilefrin …… 0.2mg
Calcium Gulconate ……. 100mg
Magnesium Gulconate …….. 10mg
Sodium Salicylate …… 7mg
Nicotinamide ……. 0.3mg
Caffeine ……. 10mg
Boric Acid ……. 10mg

3. PHARMACEUTICAL FORM

Solution for infusion

4. CLINICAL INFORMATION

4.1. Target species

Cattle & Horse.

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.
This product 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 ulcera, 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 safe use in the target species:

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 (calciumshock). 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 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, bronchospams in predisposed animal.

4.7. Use during pregnancy and lactation or lay

The use during the late phase of pregnancy requires a strict indication.
Metabolites of Novaminsulfon cross the placental barrier and penetrate into milk.

4.8. Interaction with other veterinary medicinal products and other forms of interaction

Novaminsulfon may intensify the effect of anticoagulants and attenuate the diuretic effect of furosemide. The combination of Novaminsulfon 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 Novaminsulfon. Simultaneous administration of glucocorticoids increases the risk of gastro-intestinal bleeding. Simultaneous administration of other weak analgesics intensifies the effects and adverse effects of Novaminsulfon .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. Dosage and administration route

Infuse slowly at body temperature.
Cattle/horses: 50 ml/100 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, and muscular weakness. In these cases, discontinue the infusion and if necessary start symptomatic treatment.

4.11. Withdrawal period:

Meat and offal:
Cattle: 13 days
Horse: Not Applicable:

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Pyrazolones,
ATCvet code: QN02BB52

5.1. Pharmacodynamics properties

Novaminsulfon and sodium salicylate provide pain relief and fever reduction through prostaglandin inhibition.
Etilefrine raises blood pressure, counteracting potential hypotensive effects.
Calcium and magnesium gluconate correct mineral imbalances.
Nicotinamide supports metabolic functions.
Caffeine stimulates the central nervous system, potentially enhancing alertness or counteracting the effects of other depressants.
Boric acid, if present, would have limited local antiseptic effects. However, the combined effects on the animal's cardiovascular, renal, and neurological systems are difficult to predict due to potential drug interactions and species-specific responses. The presence of boric acid raises significant safety concerns, as it's not typically used in injections due to toxicity. Therefore, careful monitoring and veterinary expertise are crucial for safe administration.

5.2. Pharmacokinetic information

Novaminsulfon, acting as an analgesic and antipyretic, is generally well-absorbed and rapidly distributed, with hepatic metabolism and renal excretion, but species variations exist.
Etilefrine, a sympathomimetic, increases blood pressure, its absorption and distribution are dependent on the injection site,
While calcium and magnesium gluconate, providing essential minerals, have absorption rates influenced by the animal's physiological state.
Sodium salicylate, an NSAID, will be absorbed and distributed, competing for protein binding sites with other drugs.
Nicotinamide, a vitamin B3 form, is rapidly absorbed, while caffeine, a stimulant, will have rapid distribution and potential interactions with other CNS-active ingredients.
Boric acid, if included, would have limited systemic absorption, and its inclusion in an injectable form is highly unusual due to toxicity risks.

6. PHARMACEUTICAL INFORMATION

6.1 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 container: use immediately, do not store.

6.4. Special precautions for storage

Store below 25°C.
Protect from light & moisture
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

6.5. Nature and composition of primary conditioning

Cardboard box with glass injection vial (s).
Vial is closed with a bromobutyl rubber stopper and sealed with an aluminum flip off seal.
Pack sizes: 100ml, 250ml, 400ml, and 500ml

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS
UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Any unused veterinary medicinal products or waste materials derived from such medicinal products should be disposed of in accordance with local requirements and placed in appropriate collection and disposal systems for unused or expired medicinal products.

7. MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 058987

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 28-08-2009

10. DATE OF REVISION OF THE TEXT

17-02-2025