SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novasul 500 mg/ml - Solution for injection for animals

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:
Metamizole sodium 500 mg

Excipient:
Benzyl alcohol 10.0 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection

4. CLINICAL PARTICULARS

4.1 Target species
Horse, cattle, pig, dog

4.2 Indications for use, specifying the target species
Treatment of pains, spasms, fever, like in case of colics, oesophageal obstruction and other spasm-like states of the abdominal organs as well as paresis.
Rheumatic conditions like acute and chronic arthritis, tendovaginitis, neuritis and neuralgias.

4.3 Contraindications
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in case of ulceration of the gastrointestinal mucosa, hepatic-, cardiac- or renal insufficiency.
Application in animals with disturbances of haematopoiesis only after accurate benefit-risk assessment.
Do not use in cats because of content of benzyl alcohol.

4.4 Special warnings for each target species
None.

4.5 Special precautions for use

Special precautions for use in animals
Do not apply subcutaneously, because irritations of the tissue may occur.
Because of a potential shock risk the intravenous application of metamizole should be done especially slowly.

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 insert or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)
The main undesirable effects of metamizole are based on hypersensitivity reactions. The most important are shock and a dose-independent haemotoxicity on allergical basis (agranulocytosis, leukocytopeny and thrombocytopeny). Both reactions are very rare despite world-wide application for many decades of metamizole.

In case of shock symptoms a symptomatic treatment (adrenalin, then corticoides, if necessary antihistamines) has to be initiated.

4.7 Use during pregnancy and lactation or lay
Can be used during pregnancy and lactation, but it has to be considered that metamizole passes the placenta. No data on possible damages of the fetus are available.

4.8 Interaction with other medicinal products and other forms of interactions
In combination with neuroleptics (especially phenothiazin derivates) severe hypothermia may occur. Simultaneous treatment with inductors of liver microsome enzymes (barbiturates, phenylbutazon) shortens the half-life period and by this the duration of action of metamizole.
When cyclosporins are applied simultaneously, the cyclosporin level can be lowered.

4.9 Amounts to be administered and administration route
For intramuscular or slow intravenous injection.

Horses	20 - 50 ml (only IV)	Pigs	10 - 30 ml
Foals	5 - 15 ml (only IV)	Piglets, dogs	1 - 3 ml
Cattle	20 - 40 ml		
Calves	5 - 10 ml		

If necessary, injections can be repeated on the same day at intervals of minimum eight hours.

4.10 Overdose (symptoms, emergency procedure, antidotes), if necessary
The risk of intoxication seems to be low and is to be expected only in case of substantial overdose.
In case of overdosage salivation, vomiting, circulatory collapse as well as increased respiration and convulsions, then coma and respiratory paralysis occur. If necessary, standard measures for maintenance of the vital functions have to be taken first.

4.11 Withdrawal periods
Meat and offal:
Horse (only IV): 6 days
Cattle: 13 days
Pig: 3 days

Milk (cattle): 2 ½ days (5 milkings)

Do not use in mares producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Pyrazolones, ATCvet code: QN02BB02

5.1 Pharmacodynamic properties

Metamizole sodium is a non acidous pyrazolone derivate with strong analgetic, good antipyretic and spasmolytic effects. Also an anti-phlogistic action is achieved, which is supposed to occur due to inhibition of prostaglandin-synthesis.
The centrally analgesic action leads to a quick sedation of animals. The spasmolysis of the smooth musculature results in a vasodilation with increased blood supply of the periphery.

5.2 Pharmacokinetic properties

Effect quickly sets in (10 - 15 minutes after IV, 30 minutes after IM application). Metamizole is metabolised to phenazine derivatives.
Excretion mainly renal, partly also via the faeces.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Water for injection.

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:
3 years.
Shelf-life after first opening the immediate packaging: 28 days.
The date of first withdrawal has to be stated on the label of the vial.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
After first opening the container do not store above 25 °C.

6.5 Nature and composition of immediate packaging

100 ml brown glass vial, glass type II, Ph.Eur. with brombutyl rubber stopper type I, Ph.Eur. and aluminium cap.
Packing size: 1 x 100ml, 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 products 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

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
Not applicable.

Available only on prescription and at pharmacies.