PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Censulfatrim 200 mg/ml + 40 mg/ml solution for injection
Censulfatrim, 200 mg/ml + 40 mg/ml solution for injection (EE)
Neuton, 200 mg/ml + 40 mg/ml solution for injection (DK)
Neuton Vet, 200 mg/ml + 40 mg/ml solution for injection (SE)

2. Composition

Each ml contains:

Active substances:

Sulfadiazine	200 mg
Trimethoprim	40 mg

Excipients:

Sodium formaldehyde sulfoxylate	1 mg
Chlorocresol	1 mg
N-methyl pyrrolidone	466 mg

A clear, yellow solution.

3. Target species

Cattle, pigs, horses, dogs and cats

4. Indications for use

Treatment of systemic infections caused by or associated with organisms sensitive to the Trimethoprim: Sulfadiazine combination.

5. Contraindications

Do not use in cases of hypersensitivity to the active substances, to sulphonamides or to any of the excipients.
Do not use by intraperitoneal route.
Do not use in cases of severe liver or kidney damage or blood dyscrasias.
Do not use in cases of reduced water intake or losses of body fluid.
Do not use in horses treated with drugs that can induce cardiac arrhythmias such as certain anaesthetic and sedative agents (e.g. detomidine).

6. Special warnings

Special warnings:

None.

Special precautions for safe use in the target species:

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the product and may decrease the effectiveness of treatment with other antimicrobials or classes of antimicrobials, due to the potential for cross-resistance.

In order to avoid impairment of the kidneys by crystalluria during the treatment adequate drinking water should be available at all times.

The intravenous route should be used with caution and only if it is therapeutically justified. If this administration route is used, the following precautions will be taken into account:
- Cardiac and respiratory shock in horses has been observed. At the first sign of intolerance the injection should be interrupted and shock treatment initiated.
- The veterinary medicinal product should be warmed to body temperature before administration.
- The veterinary medicinal product should be injected slowly over as long period as is reasonably practical.

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

This veterinary medicinal product may cause an allergic reaction in people sensitised to sulphonamides, trimethoprim or chlorocresol. People with known hypersensitivity to sulphonamides or trimethoprim should avoid contact with the veterinary medicinal product.

Administer the veterinary medicinal product with caution to avoid the accidental self-injection and the skin contact. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

This veterinary medicinal product may produce eye and skin irritation. Avoid the contact with skin and eyes. In case of contact with skin or eyes, rinse immediately with plenty of water.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established in cattle, pigs, horses, dogs and cats during pregnancy or lactation. Laboratory studies in rabbits and rats with the excipient N-methylpyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Do not administer with para-aminobenzoic (PABA) acid.

Local anaesthetics from the group of para-aminobenzoic acid esters (procaine, tetracaine) can locally inhibit the effect of sulfonamides.
Do not administer with oral anticoagulants or urinary acidifiers.
Cases of fatal cardiac arrhythmias have been observed due to interaction between sulfonamide- the trimethoprim combination and certain agents for sedating and anesthetizing horses (e.g detomidine).

Overdose:

Crystalluria and nerve and hematic disorders may occur.
In case of overdose, suspend the treatment and administer abundant water and folic acid.

Special restrictions for use and special conditions for use:

Administration by a veterinarian surgeon (in case of intravenous route) or under their direct responsibility.

Major incompatibilities:

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

7. Adverse events

Cattle, pigs, horses, dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylactic shock[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site swelling and/or tenderness[2] Crystalluria, haematuria, urinary tract obstruction/blockage blood dyscrasia NOS

[1] Particularly after the intravenous route (see section 3.5). At the first sign of intolerance the injection should be interrupted and shock treatment initiated.
[2] These lesions are of a transient nature, resolving within one week after treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

8. Dosage for each species, routes and method of administration

Intramuscular, intravenous or subcutaneous route.

Cattle, pigs and horses: 12.5 mg of sulfadiazine + 2.5 mg of trimethoprim / kg b.w., equivalent to 1 ml of veterinary medicinal product / 16 kg b.w.
- Cattle and pigs: administer by intramuscular or slow intravenous injection. Maximum recommended volume to be administered at a single intramuscular site: 15 ml of product.
- Horses: administration is by slow intravenous injection only.

Dogs and cats: 25 mg of sulfadiazine + 5 mg of trimethoprim / kg b.w., equivalent to 1 ml of veterinary medicinal product / 8 kg b.w. Administration is by subcutaneous injection only.

Treatment may be repeated until two days after the symptoms have been resolved up to a maximum of five days.

9. Advise on correct administration

To ensure a correct dosage, bodyweight should be determined as accurately as possible.

The cap may be safely punctured up to 30 times. The user should choose the most appropriate vial size according to the target species to be treated.

10. Withdrawal periods

Cattle:
Meat and offal: 12 days
Milk: 48 hours

Pigs:
Meat and offal: 20 days

Horses:
Meat and offal: 28 days
Not authorised for use in horses producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not freeze.
Keep the vial in the outer carton in order to protect from light.
Crystallisation of the product, which can occur at low temperatures, can be reversed by gentle warming.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers:

Pack sizes:
Cardboard box with 1 vial of 100 ml
Cardboard box with 1 vial of 250 ml
Cardboard box with 10 vials of 100 ml
Cardboard box with 10 vials of 250 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

CENAVISA S.L.
Camí Pedra Estela s/n
43205 Reus (SPAIN)
Tel: +34 977 75 72 73

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information