PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Individual carton boxes for 100 ml and 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CENSUTRIM 200 mg/ml + 40 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substances:

Sulfadiazine	200 mg
Trimethoprim	40 mg

3. PACKAGE SIZE

100 ml
250 ml

4. TARGET SPECIES

Cattle, pigs, horses, dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

IM, SC and IV route

7. WITHDRAWAL PERIODS

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.

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf-life after first opening the immediate container: 28 days.
Once broached/opened, use by: …/…/….

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.
Crystallisation of the product, which can occur at low temperatures, can be reversed by gentle warming.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

User warnings:
The excipient N-methyl pyrrolidone (NMP) may have 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.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

DUGV (UK) Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 56632/3000

15. BATCH NUMBER

Lot {number}

Cardboard box for 10 x 100 ml or 10 x 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CENSUTRIM 200 mg/ml + 40 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substances:

Sulfadiazine	200 mg
Trimethoprim	40 mg

3. PACKAGE SIZE

10 vials x 100 ml
10 vials x 250 ml

4. TARGET SPECIES

Cattle, pigs, horses, dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

IM, SC and IV route

7. WITHDRAWAL PERIODS

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.

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf-life after first opening the immediate container: 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

Crystallisation of the product, which can occur at low temperatures, can be reversed by gentle warming.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

User warnings:
The excipient N-methyl pyrrolidone (NMP) may have 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.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

DUGV (UK) Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 56632/3000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Labels for 100 ml and 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CENSUTRIM 200 mg/ml + 40 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substances:

Sulfadiazine	200 mg
Trimethoprim	40 mg

3. TARGET SPECIES

Cattle, pigs, horses, dogs and cats.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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.

6. EXPIRY DATE

Exp. {mm/yyyy}

Shelf-life after first opening the container: 28 days.
Once broached/opened, use by: …/…/….

7. SPECIAL STORAGE PRECAUTIONS

Do not freeze.
Crystallisation of the product, which can occur at low temperatures, can be reversed by gentle warming.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

DUGV (UK) Limited

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

CENSUTRIM 200 mg/ml + 40 mg/ml solution for injection for cattle, pigs, horses, dogs and cats

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	515 mg

A clear, yellow aqueous solution free from visible particles.

3. Target species

Cattle, pigs, horses, dogs and cats

4. Indications for use

The product is indicated in the treatment of systemic infections caused by or associated with organisms susceptible 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 in case of severe liver or kidney damage or blood dyscrasias.
Do not use in case of reduced water intake or losses of body fluid.

6. Special warnings

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 package leaflet 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.

Cross-resistance has been shown between sulfonamides. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to sulfonamides because its effectiveness may be reduced.

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.

The feeding of waste milk containing residues of trimethoprim-sulfadiazine to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

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

• This product may cause an allergic reaction in people sensitised to sulfonamides and/or chlorocresol. Hypersensitivity to sulfonamides may lead to cross reactions with other antibiotics. Allergic reactions to these substances may occasionally be serious. People with known hypersensitivity to sulfonamides or chlorocresol should avoid contact with the product.

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

- This product may cause 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 irritation persists, seek medical attention.

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

- 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.

- Wash hands after use.

Special precautions for the protection of the environment:

Not applicable

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established in cattle, pigs, horses, dogs and cats during pregnancy, lactation or in animals intended for breeding.
Laboratory studies with the excipient N-methyl pyrrolidone have shown evidence of foetal malformations in rabbits and rats. 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 and its derivatives.
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.
Administration of potentiated sulphonamides, simultaneously with alpha-2-adrenergic agents and certain anaesthetics, may cause cardiac arrhythmias in horses.

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:

Not applicable

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, renal obstruction. Alterations in haematopoietic function.

[1] Particularly after the intravenous route (see section *Special precautions for use*). 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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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 bodyweight, equivalent to 1 ml of veterinary medicinal product / 16 kg bodyweight.
- Cattle and pigs: administer by intramuscular or slow intravenous injection, once daily until 2 days after symptoms resolve up to a maximum of 5 days. Maximum recommended volume to be administered at a single intramuscular site: 15 ml of product.
- Horses: administration is by slow intravenous injection only, once daily until 2 days after symptoms resolve up to a maximum of 5 days.

Dogs and cats: 25 mg of sulfadiazine + 5 mg of trimethoprim / kg bodyweight, equivalent to 1 ml of veterinary medicinal product / 8 kg bodyweight.

Administration is by subcutaneous injection only, once daily until 2 days after symptoms resolve up to a maximum of 5 days.

9. Advice on correct administration

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

The cap may be safely punctured up to 40 times using a 20-gauge needle or up to 20 times using a 16-gauge needle. The user should choose the most appropriate vial size according to the target species to be treated.

10. Withdrawal periods

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.

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.

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.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 56632/3000

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. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

DUGV (UK) Limited,
Union House,
111 Union Street,
Coventry, CV1 2NT
UK
Tel: +353 504 43169
E-mail: pv@dugganvet.ie

Manufacturer responsible for batch release:

CENAVISA S.L.
C/dels Boters 4
43205 Reus (SPAIN)
Tel: +34 977 75 72 73

17. Other information

POM-V

Gavin Hall

Approved: 04 March 2025