1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Borgal 200 mg/ml + 40 mg/ml solution for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Sulfadoxine	200.0 mg
Trimethoprim	40.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium hydroxide
Glycerin formal
Purified water

A light brownish-yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs and horses.

3.2 Indications for use for each target species

For the treatment of primary bacterial infections and bacterial infections secondary to viral diseases in cattle, pigs and horses.

3.3 Contraindications

Do not use in pregnant animals.
Potentiated sulphonamides are contraindicated in animals with known sulphonamide hypersensitivity, severe liver or kidney parenchymal damage or blood dyscrasias.
The intravenous route of administration is contraindicated in the case of previous or concurrent administration of central nervous system depressants (e.g. anaesthetics, neuroleptics).

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

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

For intravenous administration, the injection solution should be approximately at body temperature. At the first signs of intolerance, the injection should be interrupted and shock treatment initiated. The veterinary medicinal product should be injected slowly over as long a period as is reasonably practical.

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

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, pigs, horses:

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylactic-type reaction, Hypersensitivity reaction
Undetermined frequency (cannot be estimated from the available data):	Injection site reaction[1] Cardiac and respiratory shock[2] Liver Disorder[3] Renal Disorder[3] Haematopoietic system disorder[3]

[1] Transient, after intramuscular or subcutaneous administration.
[2] In horses mostly after intravenous injection. Intravenous route of administration should therefore be used only if it is therapeutically justified.
[3] As with all trimethoprim and sulfonamide formulations.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Due to the glycerin formal content, do not use during the whole of the pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intravenous, intramuscular or subcutaneous use.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The basic dosage is 15 mg/kg b.w. relative to the total concentration of the active substance in the veterinary medicinal product equivalent to 3 ml per 50 kg b.w.

Dose according to body weight: about 3 ml of the veterinary medicinal product per 50 kg body weight.

Fully grown cattle and horses	20 - 30	ml
Young cattle, foals	5 - 15	ml
Sows	8 - 12	ml
Calves	3 - 5	ml
Older fattening pigs	5 - 8	ml
Young weaned pigs	2.5 - 3	ml
Weaned piglets	1 - 2	ml
Suckling piglets	0.5 - 1	ml

Cattle: by intravenous, intramuscular or subcutaneous injection.
Horses: by slow intravenous injection only.
Pigs: by intravenous, intramuscular or subcutaneous injection.

In cattle, the volume of injection at any site should be limited to 15 ml.

If within 24 hours no therapeutic success is achieved or if it is not sufficient, the dose may be repeated daily for a further two days.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No specific overdose reactions known.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle, pigs and horses:
Meat and offal: 10 days.

Cattle:
Milk: 96 hours.

Not authorised for use in mares producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01EW13

4.2 Pharmacodynamics

Sulfadoxine (SDO) belongs to the sulfonamide group of chemotherapeutics and Trimethoprim (TMP) to the substituted diaminopyrimidines.

The mode of action is due to a blocking effect of both substances in the bacterial folic acid metabolism at two different stages (sequential effect).

4.3 Pharmacokinetics

Both compounds of the combination are absorbed after oral or parenteral administration as the single substances. Maximal levels in blood plasma will be reached after 1-8 hours. The elimination half-time is 7-16 (up to approx. 25) hours for SDO and 0.5-3 (up to 4) hours for TMP. Sulfadoxine and Trimethoprim are distributed in all tissues with the distribution volume of TMP greater than that of SDO.

Trimethoprim is excreted after partial metabolisation (mostly by N-oxidation via urine and faeces). Sulfadoxine is predominately metabolised by N4 acetylisation. Excretion takes place mainly in the urine (as well as small amounts in milk, bile and saliva).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after first opening the immediate packaging: 6 weeks.

5.3 Special precautions for storage

Do not store above 25 °C.
Protect from light.

5.4 Nature and composition of immediate packaging

100 ml multi dose vial (Type I), closed with bromobutyl rubber stoppers and sealed with aluminium tamper-proof push-off seals.

Pack sizes:
Cardboard box with 5 x 100 ml vials.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10988/082/001

8. DATE OF FIRST AUTHORISATION

01/10/1998

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

07/03/2025

10. 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).