Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Borgal 24% Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

Sulfadoxine	200.0 mg/ml
Trimethoprim	40.0 mg/ml

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

A light brownish yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, pigs and horses.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not administer 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 contra-indicated in the case of previous or concurrent administration of central nervous system depressants (e.g. anaesthetics, neuroleptics).

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Use of the 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 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.

4.6 Adverse reactions (frequency and seriousness)

After intramuscular or subcutaneous administration transient local reactions may appear.

Cardiac and respiratory shock in horses has been observed, mostly after intravenous injection. Intravenous route of administration should therefore be used only if it is therapeutically justified.

The possibility of an anaphylactic or hypersensitivity reaction occurring following administration on rare occasions must be borne in mind.

As with all trimethoprim sulphonamide formulations the possibility of potential damage to the kidney or liver or haematopoetic system should be considered.

4.7 Use during pregnancy, lactation or lay

Due to the glycerin formal content not to be used in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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

Dose according to bodyweight: about 3 ml of the product per 50 kg bodyweight.

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.

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.

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No specific overdose reactions known.

4.11 Withdrawal Period(s)

Meat and offal: 10 days
Milk: 96 hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Combinations of sulfonamides and trimethoprim, sulfadoxine and trimethoprim.

ATCvet Code: QJ01EW13

5.1 Pharmacodynamic properties

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).

5.2 Pharmacokinetic properties

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).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydroxide
Glycerin formal
Purified water

6.2 Incompatibilities

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

6.3 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.

6.4 Special precautions for storage

Do not store above 25^{o}C. Protect from light.

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

VIRBAC SA,
1 ère avenue,
2065M, LID,
F-06516 Carros,
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10988/082/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th September 2008
Date of last renewal: 21st February 2014

10 DATE OF REVISION OF THE TEXT