1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aquaprim solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Trimethoprim	40	mg
Sulphadiazine	200	mg

Excipients:

Qualitative composition of excipient and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Glycerol Formal	
Sodium Hydroxide	
N-methylpyrrolidone	0.3 ml
Water for Injections	

A clear pale yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the treatment of diseases caused by sensitive gram positive and gram negative organisms.

3.3 Contraindications

This veterinary medicinal product should not be given by the intravenous route.

The veterinary medicinal product is contraindicated in animals with severe liver parenchymal damage or known sulphonamide sensitivity.
Not for use in horses and sheep.
Not for use in animals with severe kidney disease or blood dyscrasias.

3.4 Special warnings

The maximum dose volume recommended at any one site is:
Cattle 20 ml

Pigs 10 ml

3.5 Special precautions for use

Special precautions for safe use in the target species:

Fresh, adequate drinking water should be provided during therapy.

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.

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

Laboratory studies in rabbits and rats with the excipient N-methylpyrrolidone have shown evidence of foetotoxic effects. Women of child bearing 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.

3.6 Adverse events

Cattle and pigs:

Very rare (1 to 10 animals / 10,000 animals treated, including isolated reports):	injection site pain and erythema[1]

[1]Transient

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 and Lactation:
Potentiated sulphonamides are safe for use during pregnancy and lactation.
The safety of the veterinary medicinal product has not been established in cattle and pigs during pregnancy and lactation, or in animals intended for breeding. Use only according to the benefit-risk assessment by the responsible veterinarian.

Fertility:
Laboratory studies in rabbits and rats with the excipient N-methylpyrrolidone have shown evidence of foetoxic effects.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration route and dosage

For intramuscular use only.
The recommended dose is 12 ml per 100 kg bodyweight, daily for 3 consecutive days i.e. 24 mg SDZ per kg and 4.8 mg TMP per kg.

Species	Dose (ml)	Kg Bodyweight
Cattle	12.0	100
Calf	6.0	50
Piglet	0.6	5
Weaner	2.4	20
Fattener/sow	9.0	75

To ensure a correct dosage body weight should be determined as accurately as possible.

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

None.

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

Meat and offal: 25 days.
Milk: 72 hours.
Milk should not be used for human consumption during treatment.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC vet code:

QJ01EW10

4.2 Pharmacodynamics

Sulfadiazine belongs to the group of sulfonamide chemotherapeutics, trimethoprim belongs to the diaminopyrimidines. Both active substances have an inhibitory effect on the folic acid metabolism of microorganisms at two different stages (sequential effect). Blocking individual steps disrupts the synthesis of nucleic acids and proteins in sensitive bacteria.

Sulfadiazine inhibits the incorporation of p-aminobenzoic (PABA) acid into dihydrofolic acid. Sulfadiazine specifically competes with PABA for the enzyme dihydroproteosynthetase, this selective bacteriostatic effect depends on the difference in the formation of folic acid in bacterial and mammalian cells. Susceptible microorganisms synthesize folic acid, whereas mammalian cells use preformed folic acid.

Trimethoprim selectively inhibits the enzyme dihydrofolate reductase, thus preventing the conversion of dihydrofolic acid to tetradihydrofolic acid.

Sulfonamide resistance genes are linked chromosomally (folP genes) or extrachromosomally, e.g. to integron 1 (sul1 genes) and plasmids (sul2, sul3 genes). The result of the expression of these genes is a change in the structure of the dihydropteroate synthetase enzyme so that sulfonamides lose their ability to bind and the mechanism of their action is disrupted. There is mutual cross-resistance in the sulfonamide group.

Trimethoprim resistance genes (dfr genes) are linked chromosomally or extrachromosomally, e.g. on integrons 1 and 2 or on transposons. Extrachromosomal dfr genes are divided into two subgroups. 6 More than 30 dfr genes are currently described. Their action is manifested by a change in the structure of the dihydrofolate reductase enzyme and its sensitivity to trimethoprim. Chromosomally linked resistance is manifested either by overproduction of dihydrofolate reductase or loss of function of the thymidylate synthase enzyme.

4.3 Pharmacokinetics

Both active substances of the combination are rapidly absorbed after parenteral administration and distributed throughout the body.

Sulfadiazine is metabolized in the liver to acetylated derivatives (25%) and to a lesser extent to hydroxylated derivatives. Excretion is renal (by glomerular filtration and tubular secretion). 50% of the dose is recovered from the urine within 24 hours.

Trimethoprim is metabolized in the liver by oxidation and subsequent conjugation. Excretion is mostly renal (by glomerular filtration and tubular secretion) and to a lesser extent is excreted by bile, 75% of the dose is recovered from the urine within 24 hours and 85-90% from the urine and faeces within 3 days.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 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.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Type II (Ph. Eur.) amber glass 100 ml vial closed with a nitryl rubber stopper and sealed with an aluminium seal.

Pack Sizes
100 ml vial
12 x 100 ml vials in a cardboard/polystyrene box.

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

Univet Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10990/024/001

8. DATE OF FIRST AUTHORISATION

01/10/1988

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

04/02/2025

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*).