Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Aquaprim Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances

Trimethoprim	40 mg
Sulphadiazine	200 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and pigs

4.2 Indications for use, specifying the target species

Aquaprim Injection is indicated for the treatment of diseases caused by sensitive gram positive and gram negative organisms.

4.3 Contraindications

This product should not be given by the intravenous route.

Aquaprim Injection 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.

4.4 Special warnings for each target species

The maximum dose volume recommended at any one site is:

Cattle 20ml
Pig 10ml

4.5 Special precautions for use

Special precaution(s) for use in animals

Fresh, adequate drinking water should be provided during therapy.

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.

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

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Transient local pain and erythema may be observed at the injection site.

4.7 Use during pregnancy, lactation or lay

Potentiated sulphoamides are safe for use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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

Species	**Dose/Bodyweight**
Cattle	12.0 ml/ 100kg
Calf	6.0 ml/ 50kg
Piglet	0.6 ml/ 5kg
Weaner	2.4 ml/ 20kg
Fattner/Sow	9.0 ml/ 75kg

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

None.

4.11 Withdrawal Period(s)

Milk should not be used for human consumption during treatment or for 72 hours (3 days) thereafter.
Meat should not be used for human consumption until after 25 days after last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Phamacotherapeutic group: Antibacterials for systemic use, combinations of sulfonamides and trimethoprim
ATCvet code: QJ01EW10

Aquaprim Injection is a pale-yellow coloured sterile solution for intramuscular injection in the treatment of bacterial infections in cattle and pigs which are sensitive to potentiated sulphonamides.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol Formal
Sodium Hydroxide
N-methyl pyrrolidone
Water for Injections

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale:
3 years

Shelf life after first opening the immediate packaging:
4 weeks

6.4 Special precautions for storage

Do not store above 25°C.
Do not freeze.

6.5 Nature and composition of immediate packaging

100 ml amber glass (Type II) vial closed with a grey nitryl stopper and aluminium seal.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Univet Limited,
Tullyvin,
Cootehill,
Co. Cavan.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10990/024/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT

16th August 2010