Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Sulphamet 40/200 Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances	
Trimethoprim	40 mg
Sulphadiazine	200 mg
Excipients	
Glycerol Formal	0.3 ml

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

The product 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.
The product is contraindicated in animals with severe liver parenchymal damage or known sulphonamide sensitivity.
Fresh, adequate drinking water should be provided during therapy.
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 20 ml
Pig 10 ml

4.5 Special precautions for use

Special precautions for use in animals
None

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.

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.

SPECIES	DOSE/BODYWEIGHT
Cattle	12.0 ml/100 kg
Calf	6.0 ml/ 50 kg
Piglet	0.6 ml/ 5 kg
Weaner	2.4 ml/ 20 kg
Fattner/Sow	9.0 ml/ 75 kg

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.

Animals should not be slaughtered for human consumption during treatment or for 25 days thereafter.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The product 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

A pale yellow sterile solution in 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

Interchem (Ireland) Ltd.,
29 Cookstown Industrial Estate,
Dublin 24,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10555/005/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5th June 2006

10 DATE OF REVISION OF THE TEXT

January 2012.