

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Alfatrim 40/200 Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances

Trimethoprim 40 mg

Sulfadiazine 200 mg

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

A pale yellow sterile solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and Pigs.

4.2 Indications for use, specifying the target species

Alfatrim 40/200 is indicated for the treatment of diseases caused by sensitive gram positive and gram negative organisms in cattle and pigs.

4.3 Contraindications

This product should not be given by the intravenous route.

Alfatrim 40/200 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 dyscrasis.

4.4 Special warnings for each target species

The maximum dose volume recommended at any one site is:

Cattle: 20 ml

Pigs: 10 ml

4.5 Special precautions for use

Special precautions 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 bodyweight should be determined as accurately as possible to avoid under-dosing.

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.

Meat should not be used for human consumption until after 25 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, combinations of sulfonamides and trimethoprim ATCvet Code: QJ01EW10

5.1 Pharmacodynamic properties

When trimethoprim is administered with sulphonamides, both the formation and the reduction of bacterial dihydrofolic acid is inhibited. The sequential blockade effects by the drug combination produce an antibacterial action that is greater than the summated activity of the individual components.

5.2 Pharmacokinetic properties

Alfatrim 40/200 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 injection

6.2 Incompatibilities

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

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 nitril 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

AlfaMed Ltd.
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10894/005/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12th January 2006

10 DATE OF REVISION OF THE TEXT

3rd March 2011