## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alfatrim 40/200 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 PARTICULARS

### 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 in cattle and pigs.

### 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 dyscriasis.

### 3.4 Special warnings

The maximum dose volume recommended at any one site is:

Cattle: 20 ml
Pigs: 10

### 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<br><br>(<1 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 foetotoxic 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.
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* |

### 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

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.

### 4.3 Pharmacokinetics

This veterinary medicinal 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.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major Incompatibilities

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

### 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.

### 5.4 Nature and composition of immediate packaging

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

### 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

AlfaMed Ltd.

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA10894/005/001

## 8. DATE OF FIRST AUTHORISATION

12/01/2001

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

14/03/2024

## 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*).