SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sulfatrim (16 mg/ml + 80 mg/ml) Oral Drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances per ml:
Trimethoprim 16 mg
Sulfamethoxazole 80 mg

Excipient(s):
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral drops.
Colourless to light yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Rabbits, pigeons and Bearded Dragons.

4.2 Indications for use, specifying the target species

Treatment of gastrointestinal infections caused by protozoa (namely coccidian) sensitive to the combination of trimethoprim and sulfamethoxazole.

4.3 Contraindications

Do not use in cases with severe renal or hepatic impairment.
Do not use the product for prophylaxis.
Do not use in cases of known hypersensitivity to the active substances or the excipients.

4.4 Special warnings for each target species

This is a limited marketing authorisation and efficacy of the product is supported by a very small amount of data for the above indications. Suspected lack of efficacy of the product must be reported to the Marketing Authorisation Holder or the Veterinary Medicines Directorate.
As with all other anti-infectives, prolonged use may result in the development of resistant strains.

4.5 Special precautions for use

Special precautions for use in animals

Maintain patient hydration during treatment.
The product should be used with caution in patients with diminished renal or hepatic function, or urinary obstruction, due to the possible increased risk of side effects as a result of decreased drug clearance.

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

People with known hypersensitivity to sulfonamides should avoid contact with the veterinary medicinal product.
In case of reaction of hypersensitivity after exposure (such as skin rash), seek medical advice and show the package leaflet or the label to the physician. In case of severe reactions (swelling of the face, lips or eyes), seek prompt medical attention and take the package leaflet with you.
Take care to avoid direct contact with skin and eyes. If contact occurs, wash affected area with copious amounts of clean water. Seek medical advice if irritation persists.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Sulfonamides can cause various hypersensitivity reactions or signs of gastrointestinal disease by altering the normal gut flora.Regurgitation may be seen in birds.
CNS stimulation and myelin degeneration have been noted after very high dosages.

4.7 Use during pregnancy, lactation or lay

No studies of use of the product in pregnant or lactating animals have been conducted. Sulfonamides cross the placenta and may reach foetal levels of 50% or greater of those found in maternal serum; teratogenicity has been reported in some laboratory animals when given at very high doses. Both active substances cross the placenta and are distributed in milk. They should be used in pregnant animals only when the benefit: risk assessment by the responsible veterinarian indicates that benefits clearly outweigh the risks of therapy.

4.8 Interaction with other medicinal products and other forms of interaction

Antacids may decrease the oral bioavailability of sulfonamides if administered concurrently.
Sulfonamides may give false-positive results for urine glucose determinations when using the Benedict's method.

4.9 Amounts to be administered and administration route

For oral administration.

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid under-dosing.

Species	Dose (mg/kg) TMP+SMZ	Frequency daily	ml solution/kg	Durations (days)
Rabbit	20 - 30	2	0.2 – 0.3	10 - 14
Pigeon	25 - 50	2	0.2 – 0.5	10 - 14
Bearded dragon	15 – 20	1*	0.15 – 0.2	7 – 14

* Some literature advises alternate day dosing after the second dose has been administered.

This is a limited marketing authorisation and the above dosages are in accordance with those reported for the active substances in the target species. Any suspected adverse events or suspected lack of efficacy must be reported to the Marketing Authorisation Holder or the Veterinary Medicines

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

Sulfonamides (or their metabolites) can precipitate in the urine, particularly when given at high dosages for prolonged periods. Acidic urine or highly concentrated urine may also contribute to increased risk of crystalluria, haematuria and renal tubule obstruction.

4.11 Withdrawal period(s)

Do not use the product in animals intended for human consumption or in those animals producing eggs for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Sulfonamides and Trimethoprim.
ATCvet code: QJ01EW10.

5.1 Pharmacodynamic properties

Sulfamethoxazole acts as a false substrate in the synthesis of folic acid and trimethoprim inhibits dihydrofolate reductase. In combination, the effect is synergistic and inhibits sequential steps in the synthesis of tetrahydrofolic acid.

5.2 Pharmacokinetic particulars

Sulamethoxazole is a weak organic acid and trimethoprim is a lipid-soluble organic base. Each drug has different pharmacokinetic parameters (absorption, distribution, elimination) in each species. In combination, they are thought to be well distributed throughout the body. They are renally excreted unchanged via glomerular filtration and tubular secretion and metabolised by the liver. Sulfonamides are primarily acylated and conjugated with glucuronic acid and trimethoprim is metabolised to oxide and hydroxylated metabolites.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Coconut aroma
Sodium hydroxide
Glycerol
Glycerol formal
Water for injections

6.2 Incompatibilities

Do not mix this product with other veterinary medicinal products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after first opening the immediate packaging: 10 days
Shelf-life after dilution or reconstitution according to directions: 4 hours.

6.4. Special precautions for storage

Do not store above 25°C.
Do not refrigerate or freeze.
Protect from light.
Store in the original container.
Following dilution in tap water, any medicated water remaining after 4 hours should be discarded.

6.5 Nature and composition of immediate packaging

10 ml or 30 ml brown glass bottle (Class 3) with a low density polyethylene syringe insert and a high density polyethylene dropper screw-cap.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 36408/4008

9. DATE OF FIRST AUTHORISATION

28 March 2014

10. DATE OF REVISION OF THE TEXT

August 2021

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (EMEA) http://www.emea.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Prescription Only Medicine (POM-V)

Approved: 13/08/21

D Austin