ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

(OUTER CARTON / CARDBOARD BOX)

Read the package leaflet before use.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sulfatrim (16 mg/ml + 80 mg/ml) Oral Drops
(trimethoprim and sulfamethoxazole)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substances per ml:
Trimethoprim 18 mg
Sulfamethoxazole 80 mg

3. PHARMACEUTICAL FORM

Oral drops.

4. PACKAGE SIZE

10 ml
30 ml

5. TARGET SPECIES

Rabbits, pigeons and Bearded Dragons.

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

-

10. EXPIRY DATE

EXP month/year .....

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet carefully.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. LIMITEDS MARKETING AUTHORISATION NUMBER

Vm 36408/4008

This is a Limited Marketing Authorisation.
A full set of supporting efficacy data is not available for this product.

17. MANUFACTURER'S BATCH NUMBER

LOT .....

MINIMUM PARTICULARS TO APPEAR ON LARGE IMMEDIATE PACKAGING UNITS

(brown glass bottle with a LD polyethylene syringe insert and a HD polyethylene screw-cap**)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sulfatrim (16 mg/ml + 80 mg/ml) Oral Drops
(trimethorim and sulfamethoxazole)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S) PER GRAM

-

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
30 ml.

4. ROUTE(S) OF ADMINISTRATION

-

5. WITHDRAWAL PERIOD

-

6. BATCH NUMBER

LOT .....

7. EXPIRY DATE

EXP END (MM-YY)

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

10. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V., Woerden, The Netherlands.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

Manufacturer for the batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sulfatrim(16 mg/ml + 80 mg/ml) Oral Drops.
(trimethoprim and sulfamethoxazole).

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substances per ml:
Trimethoprim 16 mg
Sulfamethoxazole 80 mg

Excipients
Coconut aroma, sodium hydroxide (E524), glycerol (E422), glycerol formal and water for injections.

Description
A colourless to light yellow solution.

4. INDICATION(S)

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

5. 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.

6. ADVERSE REACTIONS

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.
All suspected adverse reactions and any suspected lack of efficacy should be reported to the Marketing Authorisation Holder or the Veterinary Medicines Directorate.

7. TARGET SPECIES

Rabbits, pigeons and Bearded Dragons.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Administration route
For oral adminsitration.
Amounts to be administered
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 Directorate.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C
Do not refrigerate or freeze.
Keep out of the reach and sight of children.

Do not use after the expiry date stated on the label.
Shelf-life after first opening the immediate packaging: 10 days
Shelf-life after dilution or reconstitution according to directions: 4 hours.
Store in the original container.

12. SPECIAL WARNING(S)

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.

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.

Use during pregnancy and lactation
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.

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.

Incompatibilities
Do not mix this product with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2023

15. OTHER INFORMATION

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.

Pharmacokinetic particulars

Sulfamethoxazole 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.

Package (size)

10 ml or 30 ml brown glass bottle (Class 3) with a low density polyethylene syringe insert and a high density polyethylene screw-cap. A 1.0 ml syringe is supplied with the product, capable of delivering doses of 0.05 ml.

Not all pack sizes may be marketed.

UK Distributor

Virbac Limited
Woolpit business Park
Windmill Avenue, Woolpit, Bury St. Edmunds
Suffolk IP30 9UP
United Kingdom

Pharmacovigilance phone number:

Further information on this product and its supporting data can be found on http://www.vmd.gov.uk/ProductInformationDatabase/
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 18 July 2023