SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synutrim Fortesol Powder for Oral Solution

2. QUALITATIVE & QUANTITATIVE COMPOSITION

Active ingredients

Trimethoprim	12.5% w/w
Sulfadiazine sodium	62.5% w/w

For a full list of excipients see section 6.1

Each 150 g sachet contains 93.75 g sodium sulfadiazine and 18.75 g trimethoprim.

3. PHARMACEUTICAL FORM

Powder for oral solution.
White, water soluble powder.

4. CLINICAL PARTICULARS

4.1 Target species

Swine and chickens.

4.2 Indications for use, specifying the target species

Swine: For the treatment and control of diseases sensitive to trimethoprim/sulfadiazine in pigs, in particular the respiratory disease complex.
Chickens: For the treatment and control of diseases sensitive to trimethoprim/sulfadiazine in chickens, in particular enteric and respiratory bacterial infections.

4.3 Contra-indications

None.

4.4 Special warnings for each target species

None, according to available data.

4.5 Special precautions for use

i) Special precautions for use in animals

None.

ii) Special precautions to be taken by the person administering the product to animals

Persons mixing or handling this product should avoid inhalation of any dust and contact with skin. Wear either a disposable half-mask respiratory conforming to European Standard EN149 or a non-disposable respirator to EN140 with filter EN143.
Rubber gloves should be worn when mixing or handling this product.
Contaminated clothing should be removed and any splashes to the skin or eyes should be washed immediately.
Hands and exposed skin should be washed thoroughly after use.

Sulphonamides may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to sulphonamides may lead to cross reaction with other antibiotics. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitive to sulphonamides.
2. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.

4.6 Adverse reaction (frequency and seriousness)

None recorded.

4.7 Use during pregnancy, lactation and lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For administration in the drinking water. The recommended dose of Synutrim Fortesol is 30 mg combined actives/kg bodyweight daily, given in 2 equal doses.

Chickens: This is equivalent to 1 g Synutrim Fortesol per 25 kg bodyweight birds daily. Medication period: up to 7 days.

Swine: This is equivalent to 40 g Synutrim Fortesol per 1000 kg pig weight daily. Medication period: 5 days.

The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of the active substances may have to be adjusted accordingly.

To allow ready dissolution of the Synutrim Fortesol, dissolve the required amount of product in a few litres of water before addition to the header tank.

Avoid any further dilution by securing the header tank ballcock until all the medicated water has been consumed. Once medicated water has been consumed, the ballcock can be released and non-medicated water re-supplied.

Any medicated water which is not consumed within 24 hours should be discarded.

4.10 Overdose (symptoms, emergency procedures, antidotes)

No treatment specified.

4.11 Withdrawal periods

Animals and birds must not be slaughtered for human consumption during treatment.
Swine: Pigs may be slaughtered for human consumption only after 14 days from the last treatment.

Chickens: Chickens may be slaughtered for human consumption only after 7 days from the last treatment.
Eggs from treated chickens must not be used for human consumption.

5 PHARMACOLOGICAL PROPERTIES

Mechanism of Action:
Trimethoprim and sulfadiazine are antimicrobial substances which act sequentially in the synthesis of tetrahydrofolic acid from para-aminobenzoic acid. The action of trimethoprim is to potentiate the sulfadiazine component.

5.1 Pharmacodynamic properties

Veterinary preparations contain the two active substances in a 1:5 ratio and this combination is generally effective clinically because of the relatively broad range of drug ratio over which synergism occurs.

5.2 Pharmacokinetic properties

Both active substances are absorbed well and distributed throughout the body. Excretion occurs mainly via the urine

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium lauryl sulphate
Sorbitol

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life dilution or reconstitution according to directions: 24 hours.

6.4 Special precautions for storage

Do not store above 25°C. Store in a dry place. Protect from light.
Store in tightly closed original container.
Any medicated water not consumed within 24 hours should be discarded.

6.5 Nature and contents of immediate packaging

150 g pack size: Metallised polyethylene terephthalate (12.4 µm)/low density polyethylene (70 µm) laminated sachet with a heat seal closure

2 kg pack size: Low density polyethylene bag in a white opaque polypropylene tub with a green push fit cap closure.
Dosing device: 50 ml polypropylene scoop, delivering 40 g of product.

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 if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Lilly House
Priestley Road
Basingstoke
Hampshire
RG24 9NL

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4077

9. DATE OF FIRST AUTHORISATION

4 June 1992

10. Date of revision of the text

September 2016

Approved: 30 September 2016