

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synutrim Fortesol Powder for Oral Solution

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

Active ingredients

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

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

4. PHARMACEUTICAL FORM

Powder for oral solution.

5. PACKAGE SIZE

150 g sachet

2 kg tub

6. INDICATION(S)

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.

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

Swine and chickens.

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

For administration in the drinking water

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

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.

13. SPECIAL STORAGE PRECAUTIONS

14. SPECIAL WARNING(S)

Persons mixing or handling this product should avoid inhalation of any dust and contact with skin. Wear either a disposable half-mask respirator conforming to European Standard EN149 or non-disposable respirator to European Standard 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 off 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.

15. EXPIRY DATE

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

[Distribution category]

POM-V

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

19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children

20. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4077

21. MANUFACTURER’S BATCH NUMBER

22. OTHER INFORMATION

In-vitro Synutrim Fortesol is effective against most common Gram-negative and Gram-positive bacteria including *Escherichia coli*, *Salmonella enteritidis*, *Salmonella typhimurium*, *Pasteurella multocida* and *Actinobacillus pleuropneumoniae*. Field studies in pigs have shown Synutrin Fortesol to be effective in the treatment of respiratory disease complexes caused by *Pasteurella multocida* and *Actinobacillus pleuropneumoniae*.

Approved: 05/01/2018

