PARTICULARS TO APPEAR ON THE OUTER PACKAGE - LABEL
TRIMEDIAZINE BMP PREMIX FOR MEDICATED FEEDING STUFF

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRIMEDIAZINE BMP PREMIX FOR MEDICATED FEEDING STUFF

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each kg contains:
Trimethoprim 25g
Sulfadiazine 125g

3. PHARMACEUTICAL FORM

Premix for Medicated Feeding Stuff

4. PACKAGE SIZE

Sack of 2 kg
Sack of 6 kg
Sack of 10 kg
Sack of 12 kg
Sack of 25 kg

5. TARGET SPECIES

Pigs, Sows, Chickens and Turkeys.

6. INDICATION(S)

Pigs: For the treatment of atrophic rhinitis when associated with *Bordetella bronchiseptica* and streptococcal meningitis caused by *Streptococcus suis type II*.

Chickens and Turkeys: For use in the treatment of diseases caused by bacteria sensitive to potentiated sulphonamides including infections due to salmonella and pasteurella.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pigs: Use 1.5-5.5kgs as directed of Trimediazine BMP per tonne of feed for a period of 5 days.
Sows: Depending on feed intake, bodyweight, and dosage required, incorporate into finished feed to give a dosage of 15-30mg combined active ingredients per kg bodyweight for a period of 5 days.
Chickens and Turkeys: Incorporate into finished feed at 2kg per tonne (30mg of combined active ingredients per kg bodyweight) and feed for 10 days. Where

appetite is depressed the inclusion rate should be increased to achieve the correct dosage. To ensure thorough dispersion, the product should first be mixed with 12.5kg of feed before incorporation in the final mix. This premix should be added to the mixer after 25% of the mixer load is present.

8. WITHDRAWAL PERIOD

Animals should not be slaughtered for human consumption during treatment. Animals may only be slaughtered for human consumption after the following times after the last treatment:
Pigs: 5 days **Chickens:** 1 day **Turkeys:** 3 days
Do not administer to birds producing eggs intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Incorporation into the feed must be performed by a suitably approved manufacturer. Persons handling this product should avoid inhalation of any dust and contact with skin. Wear either a disposable halfmask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with filter EN143 when mixing or handling this product. Rubber gloves should be worn when mixing or handling this product. Hands 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 reactions 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.

To avoid possible crystalluria, adequate water intake is essential. Particular care is needed with animals suffering from renal damage. Trimediazine BMP should not be administered to animals with known sulphonamide hypersensitivity. Hypersensitivity to sulphonamides has been rarely reported, however this remains a potential undesirable effect. Crystalluria caused by precipitation of insoluble sulphonamide is a theoretical risk although rarely reported. Chickens and Turkeys: where appetite is depressed the inclusion rate should be increased to achieve the correct dosage. Use in pregnancy: Data on the exact level below which no effects on foetal development were observed are not available.

However extensive use of the product in different species over many years has not shown adverse effects on the foetus. When administered to lactating females, small amounts of trimethoprim and sulfadiazine are present in the maternal milk. Since no studies have been reported of the effect on the development of new born young of the ingestion of this milk, it would be prudent not to feed very young animals with milk obtained from the mother.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Store in a dry place. Do not store above 25ºC. Store away from food, drink and animal feeding stuffs.

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

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

POM-V

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

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorization Holder:
Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

Manufacturer responsible for batch release
Vetoquinol SA, Magny-Vernois, 70200 Lure, France.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4064

17. MANUFACTURER'S BATCH NUMBER

Batch:

Approved 02 May 2018