

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON
TRIMEDIAZINE 15% PREMIX FOR MEDICATED FEEDING STUFF**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRIMEDIAZINE 15% PREMIX FOR MEDICATED FEEDING STUFF

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each kg contains:

Trimethoprim 25g

Sulfadiazine 125g

Excipient: Limestone flour to 100%

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.
Antibacterial Powder.

4. PACKAGE SIZE

Sachet of 2 kg.

Sack of 6 kg.

Sack of 8 kg.

Sack of 12 kg.

Sack of 25 kg.

5. TARGET SPECIES

Pigs, Sows, Chickens and Turkeys.

6. INDICATION(S)

Trimediazine 15% Premix is indicated for use in the treatment of diseases caused by bacteria sensitive to potentiated sulphonamides.

Chickens and turkeys: For use in the treatment of diseases caused by bacteria sensitive to potentiated sulphonamides including Salmonella infection and pasteurellosis.

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Only to be mixed with dry food.

Pigs: Incorporate into finished feed at the following rate according to feed intake and dosage required (combined active ingredients 15 to 30 mg/kg bodyweight). Administer for 5 days.

Feed intake per day per kg bodyweight	Inclusion rate per tonne of feed	
	15mg/kg	30mg/kg
Up to 35g	2.75 kg	5.5 kg
35 to 40g	2.50 kg	5.0 kg
40 to 45g	2.25 kg	4.5 kg
45 to 50g	2.00 kg	4.0 kg
50 to 55g	1.75 kg	3.5 kg
55 to 65g	1.50 kg	3.0 kg

Sows: Depending on feed intake, bodyweight and dosage required incorporate to give a dosage of 15-30mg combined active ingredients per kg bodyweight.

Chickens and Turkeys: Use 2kg Trimediazine 15% Premix per tonne of feed for a period of 10 days. Combined active ingredients 30mg/kg bodyweight. Trimediazine 15% should be premixed with at least 12.5kg of meal before adding to the mixer. This premix should be added to the mixer after 25% of the mixer load is present.

8. WITHDRAWAL PERIOD

Not for use in birds laying eggs for human consumption. Animals should not be slaughtered for human consumption during treatment. Animals may be slaughtered for human consumption only after the following times after the last treatment.

Pigs 7 days **Turkeys** 3 days **Chickens** 1 day.

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 half-mask respirator conforming to European Standard EN149 or a nondisposable 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.

Trimediazine 15% Premix should not be administered to animals with known sulphonamide hypersensitivity. To avoid possible crystalluria, adequate water intake is essential. Particular care is needed with animals suffering from renal damage. 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 effects 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. The product will remain stable in the finished feed for 6 weeks.

When incorporated at a rate below 2 kg per tonne of final feed, the product must only be mixed by a manufacturer who is approved to mix at that level.

10. EXPIRY DATE

Expiry:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in a dry place protect from light. Store away from food, drink and animal feeding stuffs. Reseal after use.

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

Dispose of any unused product and empty containers in accordance with current practice for pharmaceutical waste under national waste disposal regulations. [UK ONLY: Consult your local waste regulation authority for further information.]

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 Vm 08007/4023

POM VPA 10966/3/1 Prescription only medicine

Veterinary medicinal product authorised for use in UK and Ireland.

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

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 08007/4023

17. MANUFACTURER'S BATCH NUMBER

Batch:

A handwritten signature in black ink, consisting of several stylized, overlapping loops and a long, sweeping tail that curves downwards and to the right.

Approved 02 May 2018