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

*[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]*

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

Vétoquinol UK Limited

Vetoquinol House

Great Slade

Buckingham Industrial Park

Buckingham

MK18 1PA

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trimedoxine 80 Tablets

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

Each tablet contains Trimethoprim 80mg and Sulfadiazine 400mg.

## 4. PHARMACEUTICAL FORM

Tablet

## 5. PACKAGE SIZE

100 Tablets

500 tablets

## 6. INDICATION(S)

*[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]*

When susceptible organisms are present, the product may be effective in treating the following conditions: alimentary tract infections, respiratory and urogenital infections, skin and wound infections and eye and ear infections.

## 7. CONTRAINDICATIONS

Trimedoxine 80 tablets are not suitable for use in cats

## 8. ADVERSE REACTIONS

A low incidence of polyarthropathy and keratoconjunctivitis sicca (dry eye) has been reported in dogs following oral administration of potentiated sulphonamides. If either of these conditions occur, it is recommended that medication is stopped and that future treatment with similar products is avoided.

Sulphonamide hypersensitivity is rare in companion animals but should be considered in cases of unexpected responses to treatment.

## 9. TARGET SPECIES

Dogs

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

The daily dose is one tablet per 16kg bodyweight administered orally, providing 30mg of combined active ingredients per kg bodyweight. Treatment should be continued for up to 5 days or until 2 days after symptoms have subsided.

Overdose (symptoms, emergency procedures, antidotes), if necessary
No treatment specified.

## 11. ADVICE ON CORRECT ADMINISTRATION

## 12. WITHDRAWAL PERIOD

N/A

## 13. SPECIAL STORAGE PRECAUTIONS

Store in a dry place.

Do not store above 25°C.

Protect from light.

**[Pharmaceuticals ONLY** - *The following statement should be included if there is an in-use shelf life (example: solution for injection)]*

<When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

## 14. SPECIAL WARNING(S)<User Warnings>

Wash hands after use.

If accidental ingestion occurs, seek medical advice immediately.

For animal treatment only

**15. EXPIRY DATE**

**16. 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.

**17. DATE ON WHICH THE LABEL WAS LAST APPROVED**

*[It is mandatory for Exceptional Marketing Authorisations and recommended for others that the following reference to the VMD Website is included:]*

<Find more product information by searching for the Product Information Database 'PID' on www.gov.uk.>

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

*[Distribution category]*

POM-V

**19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"**

**20. MARKETING AUTHORISATION NUMBER(S)**

**Vm** 08007/4055

**21. MANUFACTURER'S BATCH NUMBER**

**<22. OTHER INFORMATION>**

**Approved: 11/04/2018**