PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGE {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxicure, 30% w/w Powder for Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Amoxicillin 30.0 % w/w (as amoxicillin trihydrate) 1500 mg – excip. ad 5 g

3. PHARMACEUTICAL FORM

Powder for oral suspension

4. PACKAGE SIZE

5. TARGET SPECIES

Pigeons

6. INDICATION(S)

Treatment of bacterial infections in pigeons such as streptococcosis

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage: 1 level scoop per 1 litre of drinking water (use the scoop included). For complete instructions see leaflet.

8. WITHDRAWAL PERIOD

Do not use in pigeons intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins/cephalosporins may occasionally cause severe allergic reactions.

See package leaflet for user warnings, disposal advice etc.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Store in a dry place.
Do not store above 25 °C.
Any medicated water which is not consumed within 12 hours should be discarded.

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]*

POM-V

For animal treatment only

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Oropharma n.v.
70 Kapellestraat
BE-9800 Deinze

16. MARKETING AUTHORISATION NUMBER(S)

Vm 13058/4004

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR:

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

Oropharma n.v.

70 Kapellestraat

BE-9800 Deinze

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxicure, 30% w/w powder for oral solution

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

Amoxicillin 30.0 % w/w (as amoxicillin trihydrate) 1500 mg – excip. ad 5 g

4. INDICATION(S)

Amoxicure, 30% w/w powder for oral solution and administratio is indicated for the treatment of infections caused by micro-organisms sensitive to amoxicillin such as *Streptococcus gallolyticus*. Official, national and regional antimocrobial policies should be taken into account when the product is used.

5. CONTRAINDICATIONS

Pigeons with a known hypersensitivity for penicillins should not be treated with the product.

Do not administer when β-lactamase producing bacteria are present.

6. ADVERSE REACTIONS

7. TARGET SPECIES

Pigeons not intended for human consumption

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

Dissolve the contents of one level 5 g scoop in 1 litre of drinking-water (daily ration for 20 pigeons). This gives a solution containing 1.5 mg/ml amoxicillin and provides a dose rate of 150 mg/kg bodyweight.

During treatment pigeons should not be allowed to drink from other sources. Renew the solution every 12 hours. A course of treatment normally lasts five days. In case of severe infections it is recommended to treat the pigeons for a longer period.

The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of amoxicillin has to be adjusted accordingly.

9. ADVICE ON CORRECT ADMINISTRATION

During treatment pigeons should not be allowed to drink from other sources. The drinking fountains have to be cleaned and disinfected in order to prevent reinfections. The medicated drinking water should not be prepared and held in metal drinkers.

10. WITHDRAWAL PERIOD(S)

Amoxicure must not be used in pigeons intended for human consumption

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a dry place.
Do not store above 25 °C.
Any medicated water which is not consumed within 12 hours should be discarded.

12. SPECIAL WARNING(S)

Avoid skin contact and accidental ingestion. Whilst handling the product wear coveralls, protective goggles and chemically resistant impermeable gloves at all times.

Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

2. Handle this product with great care to avoid exposure taking all recommended precautions.

3. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or

eyes or difficulty in breathing are more serious symptoms and require urgent medical attention. Wash hands after use.

For Animal Treatment Only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. Dispose of unused medicated water onto pigeon excreta in the loft. Do not spread excreta from medicated birds on land used for growing crops.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

POM – V To be supplied only on veterinary prescription

Vm 13058/4004

Approved: 10/01/2018