

SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxicure, 30% w/w powder for oral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients

Amoxicillin (as amoxicillin trihydrate) 30.0 % w/w

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for oral solution.

Very fine, microcrystalline, white or almost white, almost odourless or with a faint characteristic odour of amoxicillin powder.

4. CLINICAL PARTICULARS

4.1 Target species

Pigeons.

4.2 Indications for use, specifying the target species

Indicated for the treatment of infections caused by micro-organisms sensitive to amoxicillin such as *Streptococcus gallolyticus*.

4.3 Contra-indications

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

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. Special precautions for use in target animals

Official, national and regional antimicrobial policies should be taken into account when the product is used.

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.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

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.

4. Wash hands after use.

iii. Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

Penicillins can induce allergic reactions.

4.7 Use during pregnancy, lactation or lay

The use of the product should be avoided during breeding unless the veterinarian decides that treatment with amoxicillin is necessary.

4.8 Interaction with other medicinal products and other forms of interaction

Aminoglycoside antibiotics have a synergistic effect when they are administered together with amoxicillin.

Amoxicillin is only bactericidal against growing bacteria. Simultaneous administration of bacteriostatic antibiotics or chemotherapeutics such as tetracyclines or sulphonamides diminishes the working of amoxicillin and should be avoided.

4.9 Amount(s) to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Gastro-intestinal symptoms (vomiting, diarrhoea) can be seen with an overdose. These symptoms are reversible and no specific treatment is necessary.

No side effects are seen when the recommended dose is administered for a longer treatment period.

4.11 Withdrawal period(s)

Do not use in pigeons intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

β -lactam antibiotics, penicillin

ATC Vet Code:

QJ01CA04

5.1 Pharmacodynamic properties

Amoxicillin has a high therapeutic activity against a number of Gram-positive and Gram-negative organisms. *Streptococcus gallolyticus*, *Salmonella typhimurium*, *E. coli* and *Staphylococcus intermedius* are the most important amoxicillin sensitive organisms encountered in pigeon infections.

Amoxicillin predominantly inhibits side-wall synthesis in susceptible bacteria by blocking the synthesis of mureine (peptidoglycan layer). This structure gives the wall its strength and permits it to resist the high intracellular osmotic pressure. Mureine consists of linear chains of alternating N-acetyl glucosamine and N-acetyl muramic-acid, which are linked transversally with short peptide chains. Amoxicillin competitively inhibits the enzyme transpeptidase, necessary for the transversal linking. In consequence, the side-wall of the growing bacteria loses solidity and can not longer resist the increasing pressure from inside the cell. This leads to rupture of the cytoplasmic membrane through the weakened section and formation of a spheroplast. Bursting of the spheroplast and lysis of the cell follow. Amoxicillin affects growing cells and has little effect on dormant bacteria (those in the resting phase). Thus administration of a bacteriostatic drug concomitantly with amoxicillin is not appropriate, since bacteriostatic suppression may inhibit the bactericidal action of penicillins in general (Yeoman, 1977; Krieg, 1986; Huber, 1988) (31, 16, 13).

5.2 Pharmacokinetic particulars

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Carbonate Monohydrate
Silica Colloidal Anhydrous
Disodium Edetate Dihydrate
Lactose Monohydrate

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after dilution or reconstitution according to directions: 12 hours.

6.4 Special precautions for storage

Store in a dry place.

Do not store above 25 °C.

Any medicated water which is not consumed within 12 hours should be discarded.

6.5 Nature and composition of immediate packaging

120 g polypropylene tubs lined with a polyethylene bag, closed with low density polyethylene push fit lids. The 120 g tub is supplied with a 5 g polystyrene scoop, which a level spoonful supplies 1500 mg of Amoxicilline

The authorised pack size

1 tub with 120 g powder and a 5 g scoop.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Unused medicated water should be disposed of by pouring onto excreta in the loft.

Excreta from treated birds should not be spread on land used for growing crops.

7 MARKETING AUTHORISATION HOLDER

Oropharma n.v.
70 Kapellestraat
BE-9800 Deinze

8. MARKETING AUTHORISATION NUMBERS

Vm 13058/4004

9. DATE OF FIRST AUTHORISATION

Date: 2nd April 2000

10. DATE OF REVISION OF THE TEXT

Date: 23rd October 2008