1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Octacillin 800 mg/g powder for use in drinking water for chickens

NL: Octacillin 800 mg/g poeder voor gebruik in het drinkwater voor kippen
DE: Octacillin 800 mg/g Pulver zum Eingeben über das Trinkwasser für Hühner
FR: Octacillin 697 mg/g poudre pour administration dans l'eau de boisson des poulets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 gram of powder contains:
Active substance:
Amoxicillin trihydrate 800 mg corresponding to 697 mg amoxicillin

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for use in drinking water
White to pale yellow-white powder

4 CLINICAL PARTICULARS

4.1 Target species

Chicken (broiler, pullet, breeder).

4.2 Indications for use, specifying the target species

Chickens (excluding laying birds producing eggs for human consumption):
Where clinical disease is present in the flock, treatment and prevention of respiratory or gastrointestinal disease due to pathogens sensitive to amoxicillin.

4.3 Contraindications

None known for this target species.
Do not use in lagomorphs and rodents such as rabbits, guinea pigs, hamster and gerbils as this may cause severe enterotoxaemia.

4.4 Special warnings for each target species.

None.

4.5 Special precautions for use

Special precautions for use in animals
Use of the product should be based on susceptibility testing and it should take into account official and local antimicrobial policies. Resistance against amoxicillin may vary. Therefore the use of the product should be based on culture and sensitivity of micro-organisms from diseased cases on farm or from recent previous experience on the farm.
Inappropriate use of the product may increase the prevalence of bacteria resistance to amoxicilline and may decrease its effectiveness.
Special precautions to be taken by the person administering the veterinary medicinal product to animals
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations. Wear gloves and a respirator or dust mask.
Handle this product with care to avoid exposure, taking all recommended precautions. In the event of skin contact wash exposed skin with soap and water.

If you develop symptoms following exposure, such as 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.

4.6 Adverse reactions (frequency and seriousness)
None known.

4.7 Use during pregnancy, lactation or lay
Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction
Do not combine with bacteriostatic antibiotics.

4.9 Amounts to be administered and administration route
Chickens: 20 mg amoxicillin per kg body weight per day for 3-5 days administered in the drinking water. This corresponds to 28.7 mg product per kg body weight.
Prepare an amount of medicated water to be consumed within the next 12 hours. Any unused medicated water should be discarded after 12 hours, and fresh medicated water - for the next 12 hours - should be prepared.
The following formula may be used to calculate the amount of the product (in grams) required per day per 1000 litre drinking water.

$$\text{grams product per day per 1000 litre} = \frac{\text{number of birds x average live weight (kg) x 28.7}}{\text{total water intake (in litres) of the flock per day}}$$

The use of suitably calibrated weighing equipment for the administration of the calculated amount of the product is recommended. It is recommended - after addition of the powder to the drinking water - to thoroughly stir until the product is completely dissolved.
In case of a change in the drinking water intake in poultry , the concentration needs to be adjusted in such a manner that the recommended dosage in mg active ingredient per kg body weight is realised.
During the treatment period animals should not have access to other water sources than the medicated water.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
None known.

4.11 Withdrawal periods
Meat and offal: 1 day
Not permitted for use in laying birds producing eggs for human consumption.
Do not use within 4 weeks before the onset of the laying period.

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: penicillins with extended spectrum
ATC vet code: QJ01CA04

5.1. Pharmacodynamic properties

Amoxicillin, is a broad-spectrum penicillin with bactericidal antibiotic action against many Gram+ and Gram - bacteria Amoxicillin is acid resistant, but is not resistant to the action of beta-lactamases.

5.2 Pharmacokinetic properties

Amoxicillin is rapidly and almost completely absorbed from the gastrointestinal tract.
Following administration of a pulse-dosage (half the daily dose in 3 hours) of 10.5 mg amoxicillin per kg body weight a Cmax of 1.3 µg/ml was reached within 1.1 hour after the start of the medication in chickens. The elimination half life was 1.7 hour. Following repeated pulse-medication no accumulation occurred.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium carbonate monohydrate
Sodium citrate
Silica colloidal anhydrous

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

- Shelf life of the veterinary medicinal product as packaged for sale: 3 years
- Shelf life after first opening the immediate packaging: 3 months
- Shelf life after dilution or reconstitution according to directions: 12 hours.

6.4 Special precautions for storage

Keep the bag tightly closed after first opening in order to protect from moisture.

6.5 Nature and composition of immediate packaging

Sachets consist of a white layer on the outside, inside different transparent layers, a sub-layer of aluminium and an inner layer of polyethylene. Pack sizes are 100 g, 250 g, 500 g and 1.0 kg.
Sachets consist of a polyester layer on the outside, inside layers of aluminium and polyamide and an inner layer of polyethylene. Pack sizes are 100 g, 250 g, 500 g and 1.0 kg.
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

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

7. MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.,
Handelsweg 25, 5531 AE Bladel, The Netherlands.

8. MARKETING AUTHORISATION NUMBER

{*Number allocated by MS}*

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

XX / XX / XXXXX

10 DATE OF REVISION OF THE TEXT

XX-XX-2014

Part IB-2

LABELLING

OCTACILLIN
POWDER FOR USE IN DRINKING WATER
FOR CHICKENS

The full text will be printed on the sachet/bag
Format used is required by Dutch law for this type of labelling

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

=

IMMEDIATE PACKAGE

=

LEAFLET

Plastic/Aluminium sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Octacillin 800 mg/g powder for use in drinking water for chickens
NL: Octacillin 800 mg/g poeder voor gebruik in het drinkwater voor kippen

Amoxicillin trihydrate
DE: Octacillin 800 mg/g Pulver zum Eingeben über das Trinkwasser für Hühner
Amoxicillin trihydrate
FR: Octacillin 697 mg/g poudre pour administration dans l'eau de boisson des poulets
Amoxicillin

2. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 gram of powder contains:

Active Substance: Amoxicillin trihydrate 800 mg corresponding to 697 mg amoxicillin

3. PHARMACEUTICAL FORM

Powder for use in drinking water. White to pale yellow-white powder.

4. PACKAGE SIZE

100 g, 250 g, 500 g, 1.0 kg.

5. TARGET SPECIES

Chicken (excluding laying birds producing eggs for human consumption): broiler, pullet, breeder.

6. INDICATION(S)

Chickens (excluding laying birds producing eggs for human consumption):
Where clinical disease is present in the flock, treatment and prevention of respiratory or gastrointestinal disease due to pathogens sensitive to amoxicillin.

7. CONTRAINDICATIONS

None known for this target species.
Do not use in lagomorphs and rodents such as rabbits, guinea pigs, hamster and gerbils as this may cause severe enterotoxaemia.

8. ADVERSE REACTIONS

None known.

If you notice any serious effects or other effects not mentioned in this product information, please inform your veterinary surgeon or pharmacist.

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

Chickens: 20 mg amoxicillin per kg body weight per day for 3-5 days administered in the drinking water. This corresponds to 28.7 mg product per kg body weight.

Prepare an amount of medicated water to be consumed within the next 12 hours. Any unused medicated water should be discarded after 12 hours, and fresh medicated water - for the next 12 hours - should be prepared.
The following formula may be used to calculate the amount of product (in grams) required per day per 1000 litre drinking water.

$$\text{gram product per day per 1000 litre} = \frac{\text{number of birds x average live weight (kg) x 28.7}}{\text{total water intake (in litres) of the flock per day}}$$

The use of suitably calibrated weighing equipment for the administration of the calculated amount of product is recommended. It is recommended - after addition of the powder to the drinking water - to thoroughly stir until the product is completely dissolved.

10. WITHDRAWAL PERIODS

Meat and offal: 1 day
Not permitted for use in laying birds producing eggs for human consumption.
Do not use within 4 weeks before the onset of the laying period.

11. SPECIAL WARNINGS

Special precautions for use in animals
Use of the product should be based on susceptibility testing and it should take into account official and local antimicrobial policies. Resistance against amoxicillin may vary. Therefore the use of the product should be based on culture and sensitivity of micro-organisms from diseased cases on farm or from recent previous experience on the farm
Inappropriate use of the product may increase the prevalence of bacteria resistance to amoxicilline and may decrease its effectiveness.
In case of a changed in drinking water consumption, the concentration should be adjusted such that the recommended dosage in mg active ingredient per kg body weight is realised. During the treatment period animals should not have access to other water sources than the medicated water.
Special precautions to be taken by the person administering the veterinary medicinal product to animals
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Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations. Wear gloves and a respirator or dust mask.
Handle this product with care to avoid exposure, taking all recommended precautions. In the event of skin contact wash exposed skin with soap and water.
If you develop symptoms following exposure, such as 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.
Lay:
Not applicable.
Interactions with other medicinal products and other forms of interaction
Do not combine with bacteriostatic antimicrobial agents
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
Overdose (symptoms, emergency procedures, antidotes)
None known.

12. EXPIRY DATE

EXP {month/year}

Once opened/broached, use by:

13. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf-life after first opening the packaging: 3 months.
Keep the bag tightly closed after first opening in order to protect from moisture
Shelf-life after dilution or reconstitution according to directions: 12 hours.

14. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

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

15. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

For animal treatment only.
Prescription only medicine

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

Keep out of the sight and reach of children.

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

Eurovet Animal Health BV, Handelsweg 25, 5531-AE Bladel, The Netherlands

18. MARKETING AUTHORISATION NUMBER(S)

{*Number allocated by MS}*

19. MANUFACTURER'S BATCH NUMBER

Lot {number}

20. DATE ON WHICH THE TEXT WAS LAST APPROVED

XX/XX/2014

21. OTHER INFORMATION

Pack sizes: 100 g, 250 g, 500 g and 1.0 kg.

Not all pack sizes may be marketed.