SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetremox 100% w/w Powder for Use in Drinking Water

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

Qualitative composition	Quantitative composition % w/w
Amoxicillin trihydrate	100

Excipients

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for use in drinking water
A fine white to cream coloured powder

4. CLINICAL PARTICULARS

4.1 Target species

Chickens and turkeys

4.2 Indications for use, specifying the target species

E. coli, Pasteurella spp and Erysipelothrix spp infections in chickens.
Pasteurella Multocida infection in turkeys.

4.3 Contraindications

In common with all other penicillins, amoxicillin should not be used orally or parenterally in rabbits, guinea pigs, hamsters, gerbils or other very small herbivores.

4.4 Special warnings for each target species

No special warnings

4.5 Special precautions for use

i. Special precautions for use in animals

For oral use only

ii. Special precautions for the person administering the veterinary medicinal product to animals

Avoid skin contact. 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.
When adding the product to water, keep the neck of the powder container below the level of the water while emptying, in order to minimize the presence of dust.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reaction 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 sensitized, 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.

iii. Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

Adverse reactions are rarely encountered. Hypersensitivity reactions may occur. If suspected adverse reactions do occur, treatment should be discontinued immediately.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during lay

4.8 Interaction with other medicinal products and other forms of interaction

Not to be administered with other antibacterials.

4.9 Amount(s) to be administered and administration route

Dosage:
The dose rate is 20mg/kg body weight.
Chickens: This dose should be administered daily during 3 to 5 days depending on the clinical response.
Turkeys: The dose should be administered on day 1, 3 and 5 of the treatment period.

Calculate the quantity of Vetremox powder required to provide one dose to all of the birds in the affected house and administer this via drinking water.

Administration
When administered via a header tank:
First add the required quantity of Vetremox powder to 10 litres of tepid water in clean container and stir vigorously for one minute.
Then immediately add this stock solution to the header tank and stir gently.
N.B. Very hard mains water may produce some cloudiness when Vetremox Powder had been added but this will not affect the drug in any way.
Turn of the water supply to the header tank until all the medicated water has been consumed.
After all the medicated water has been consumed, resume the supply of unmedicated water.

Portable drinkers may be used for young birds or small groups of birds.

Do not supply medicated and unmedicated water at the same time.

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

None

4.11 Withdrawal period(s)

Meat and offal:

Chickens – 1 day
Turkeys – 5 days

Eggs

Not authorised for use in laying birds producing eggs for human consumption. Do not use within 14 days of the onset of laying.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use

ATC Vet Code: QJ01CA04

5.1 Pharmacodynamic properties

The active ingredient, amoxicillin, is a bactericidal antibiotic of the beta-lactam class.
It acts by inhibition of bacterial cell wall synthesis. Amoxicillin is not resistant to the action of beta lactamases, which can hydrolyse the molecules causing the beta-lactam ring structure to open, rendering it antibiotically inactive.
The information for staphylococcal beta-lactamase is encoded in a plasmid and may be transferred by bacteriophage to other bacteria. In G-bacteria beta-lactamases are encoded in either chromosomes or in plasmids and they may be constitutive or inducible. Plasmids may be transferred between bacteria through conjugation.
Some bacteria are intrinsically resistant to amoxicillin, because they have decreased affinity for the antibiotic. Decreased affinity may also be acquired by homologous recombination between genes of different species. Other instances of bacterial resistance are caused by the inability of the agent to penetrate to its site of action (some G-bacteria) or by energy dependent efflux systems for pumping the antibiotic out of the bacteria.
In general, practical development of resistance in vitro against amoxicillin like all penicillins occurs slowly and stepwise, with an existing cross-resistance with other penicillins which is of practical significance by staphylococci.
Both long term treatment and sub-therapeutic dosages can select for antimicrobial resistance. Amoxicillin is generally active against some Gram-negative and most Gram-positive bacteria e.g. penicillin sensitive Staphylococci, Streptococci, Pasteurella spp., Clostridium spp., Salmonella spp., *Haemophilus paragallinarum*, and *E. coli*. Resistance amongst *E. coli* is not uncommon.

5.2 Pharmacokinetic properties

Following oral medication amoxicillin is rapidly absorbed. Serum protein binding is low. Amoxicillin is widely distributed throughout the body. Amoxicillin is mainly eliminated via the kidneys is the active form. A smaller part of the administered dose of amoxicillin is excreted in the bile.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months
Shelf life after dilution or reconstitution according to directions: 24 hours

6.4 Special precautions for storage

i. Do not store above 25°C.
ii. Store in a dry place.
iii. Store tightly closed in the original container.
iv. Any medicated water which has not been consumed within 24 hours, should be discarded.

6.5 Nature and composition of immediate packaging

75g, 200g and 500 white, polypropylene tubs with white, low density polyethylene lids (push-fit). Not all packsizes 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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4166

9. DATE OF FIRST AUTHORISATION

17 September 1990

10. DATE OF REVISION OF THE TEXT

November 2020

Approved 06 November 2020