SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetramin 200 Powder Premix for Medicated Feed

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each kilogram contains 200 g oxytetracycline (as oxytetracycline dihydrate) in a limestone vehicle.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Premix for medicated feed.
Mid to light brown or light yellow powder premix for incorporation into feedstuffs.

4. CLINICAL PARTICULARS

4.1. Target species

Pigs.

4.2. Indications for use, specifying the target species

For use as an aid in the control of respiratory diseases caused by bacteria sensitive to oxytetracycline.

4.3. Contraindications

None.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

i) Special precautions for use in animals

Long term use of this product may lead to development of bacterial resistance and is not recommended. However, the recommended course of treatment should be completed.

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

If you know you are allergic to oxytetracycline, do not handle the product. When incorporating into feed, care should be taken not to inhale any dust when handling the product and skin contact should be avoided. It is recommended that a face mask, conforming to EN140 with a filter to EN143, be worn during the dispensing of the product. Hands and exposed skin should be washed thoroughly at the end of the operation.

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

The presence of high concentrations of divalent or trivalent ions e.g. Ca^{2+}, may reduce absorption of oxytetracycline due to formation of chelates with no antimicrobial activity. This is only a practical consideration in animals fed milk or milk replacer.

4.9. Amounts to be administered and administration route

20 mg/kg bodyweight per day in feed for 15 days.

The following inclusion rates may be used as a guide to obtaining this dose in normal and inappetant pigs.

Food intake expressed as a percentage of animal bodyweight	Inclusion rate, kg of product per 1000kg of feed
5% (normal)	2 kg
4% (inappetant)	2.5 kg
3% (inappetant)	3.25 kg
2% (inappetant)	5 kg

To ensure thorough dispersion of the product, it should first be mixed with a suitable quantity of feed before incorporation in the final mix. If this product is incorporated in an intermediate feedingstuff, care should be taken to ensure that the intermediate feedingstuff is incorporated at a rate which will yield the same concentration of active ingredient as stated in the dosage schedule.

For incorporation into dry feed at the registered mill.

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

The safety margin of oxytetracycline in the target species is very wide and toxic signs are unlikely to be seen.

4.11. Withdrawal period

Animals must not be slaughtered for human consumption during treatment. Pigs may be slaughtered for human consumption only after 5 days from the end of last treatment.

5. PHARMACOLOGICAL PROPERTIES

ATCVet Code: QJ01AA06

Oxytetracycline (OTC) is a broad-spectrum antibiotic. Its mode of action is bacteriostatic by inhibition of prokaryotic protein synthesis at the ribosomal level. It is active against Gram-positive and Gram-negative aerobic and anaerobic micro-organisms, *Mycoplasma* spp., *Chlamydia* spp., *Leptospira* spp. and Rickettsias. It has little activity against *Salmonella* spp., *Escherichia coli*, Enterobacter and *Klebsiella* spp. and has essentially no activity against *Pseudomonas* spp., *Proteus* spp. and yeasts. Sub-Minimum Inhibitory Concentration (MIC) effects have been identified for tetracyclines. Inhibition of adhesion of pathogens to host cell surfaces are known to occur at levels of antibiotic lower than the MIC. Host cell adhesion is an essential pre-requisite for the expression of pathogenicity for several porcine respiratory pathogens e.g. *Actinobacillus pleuropneumoniae*, *Bordetella brochiseptica* and mycoplasmas.

Selected resistance to tetracyclines is not uncommon among bacteria and it is important that sensitivity is determined prior to initiation of therapy. Most organisms which are resistant to one member of the tetracycline group will have cross-resistance to other members of the group.

Due to the amphoteric nature of OTC, oral bioavailability is low (<10%). OTC has excellent distribution properties with a Volume of Distribution (Vd) exceeding 1.2 L/kg. The compound tends to concentrate in the lung, liver and kidney. OTC undergoes enterohepatic circulation. It does not appear to be metabolised to any significant degree. The compound is mainly excreted as the parent molecule primarily in the urine but also in the faeces.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Light Liquid Paraffin
Limestone Flour

6.2. Incompatibilities

None.

6.3. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.
The product is stable during pelleting and in pelleted and unpelleted feed for up to 3 months and in protein concentrates and vitamin/mineral premixes for 6 months.

6.4. Special precautions for storage

Do not store above 25°C. Store in a dry place. Protect from light.

6.5. Nature and composition of immediate packaging

Supplied in 2 kg polyester/aluminium foil/polyethylene bag or polyethylene bag. 25 kg supplied in multi-walled paper sack with polyethylene liner.

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.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4153

9. RENEWAL OF THE AUTHORISATION

Date: 28 January 2002

10. DATE OF REVISION OF THE TEXT

Date: March 2014


26 March 2014