SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMOX

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1g of product contains:

Oxytetracycline (as hydrochloride)..... ….500mg
Excipient..... qs 1 g

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral powder for use in drinking water.
Yellow powder

4. CLINICAL PARTICULARS

4.1. Target species

Calves, lambs, kids, pigs, rabbits and poultry.

4.2. Indications for use, specifying the target species

In calves, lambs, kids, pigs, rabbits and poultry:

Treatment and prevention at the group level of septicaemia, respiratory and gastrointestinal infections caused by bacteria sensitive to oxytetracycline.

4.3. Contraindications

Do not use in case of hypersensitivity to oxytetracycline or any other substance from tetracyclines group.

Do not use in cases of known oxytetracycline resistance.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

i) Special precautions for use in animals

This powder should be dissolved in milk, in liquid feed or in water, before use.

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

People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.

Avoid inhaling dust when handling the product until complete solubilisation in water. Use in a well-ventilated area away from draughts.

Avoid contact with skin and eyes.

Personal protective equipment consisting of latex and nitrile gloves, eye protection dust mask (either a disposal half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143) and suitable protective clothing should be worn when handling the veterinary medicinal product. In case of accidental eye or skin contact, rinse the affected area with large amounts of clean water. If irritation occurs, seek medical advice immediately and show the label to the physician.

Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands and contaminated skin immediately after handling the product.

Do not smoke, eat or drink while handling the product.

iii) Other precautions

None.

4.6. Adverse reactions (frequency and seriousness)

As for all other tetracyclines, side effects have been observed such as gastro-intestinal disorder and less frequently, allergic and photosensitivity reactions.

4.7. Use during pregnancy, lactation or lay

Laboratory studies in animals have not produced any evidence of embryotoxicity or teratogenic effects.

In mammals, oxytetracycline pass the placental barrier, resulting in staining of teeth and slow foetal growth.

Tetracyclines are found in breast milk. The product safety has not been evaluated on pregnant or lactating females.

Use on pregnant or lactating females only according to the benefit/risk assessment by the responsible veterinarian.

4.8. Interaction with other medicinal products and other forms of interaction

Divalent or trivalent cations (Mg, Fe, Al, Ca) may chelate with tetracyclines. The tetracylines should not be administered with antacids, gels containing aluminium, preparations containing vitamins or minerals as insoluble complexes will be formed, which decreases the absorption of the antibiotic.

4.9. Amount(s) to be administered and administration route

The uptake of medicated drinking water depends on the clinical and physiological conditions of the animals. In order to obtain the correct dosage, the concentration of oxytetracycline must be adjusted by calculating the required meandaily water consumption.

Calves, lambs, kids and pigs:

20mg of oxytetracycline / kg of bodyweight / day for 3 to 5 days, corresponding to 400mg of powder for 10 kg of bodyweight / day taken twice daily in milk, liquid feed or drinking water.

Rabbits and poultry:

20mg of oxytetracycline / kg of bodyweight / day for 3 to 5 days in drinking water. The concentration of the medicine in water is detailed in the table below, for an estimated water consumption:

Species	**mg of oxytetracycline / kg of bodyweight / day**	**mg of ORAL POWDER / 10 kg of bodyweight / day**	**Estimated water consumption (L / 10 kg of bodyweight)**	**mg of ORAL POWDER / L of drinking water**
Rabbits	20 mg	400 mg	1.8 L / 10 kg	220 mg /L
Chickens	20 mg	400 mg	2 L / 10 kg	200 mg /L

Based on the recommended dose, the number and weight of the animals to be treated, the exact daily amount of oxytetracycline should be calculated according to the following formula:

$$\frac{\text{mg oxytetracycline / kg body weight / day} \times \text{Mean body weight (kg) of animals to be treated}}{\text{Mean daily water consumption (L) per animal}} = \text{mg oxytetracycline per litre drinking water}$$

To ensure a correct dosage, the anima body weight should be determined as accurately as possible to avoid underdosing.

The use of suitability calibrated weighing equipment is recommended if part packs are used. The daily amount is to be added to the drinking water such that all medication will be consumed in 24 hours.

Medicated drinking water should be freshly prepared every 24 hours.

For full advantages of solubility qualities, it is recommended to prepare a concentrated pre-solution – approximately 400 grams of product per litre drinking water – and to dilute this further to therapeutic concentrations if required. Alternatively, the concentrated solution can be used in a proportional water medicator.

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

Refer to section 4.6 “Adverse reactions (frequency and seriousness)”.

4.11. Withdrawal period

Meat and offal: 7 days
Eggs: zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, tetracycline
ATCvet code: QJ01AA06.

5.1. Pharmacodynamic properties

The oxytetracycline links reversibly to the ribosomal subunit 30S receptors, this leading to a blockage of the union between aminoacyl-tRNA to the site corresponding to the mRNA-ribosome complex messenger.
It results in an inhibition of the protein synthesis and inhibits bacterial growth. The mainly bacteriostatic activity of oxytetracycline involves uptake of the substance into the bacterial cell which occurs by both passive and active diffusions. The main mechanism of resistance is due to the possible presence of a R factor responsible for a decrease in the active transport of oxytetracycline.

Oxytetracycline is a broad-spectrum antibiotic. It is mainly active against Gram-positive and Gram negative bacteria, aerobic and anaerobic, as well as against mycoplasma, the Chlamydia and Rickettsiae.

Acquired resistance to oxytetracycline has been reported. This resistance is usually of plasmid origin. Cross-resistance to other tetracyclines is possible. A continuous treatment with low doses of oxytetracycline may also cause increased resistance to other antibiotics due to potential co-resistance with other antimicrobials.

5.2. Pharmacokinetic particulars

For the majority of species, oxytetracycline is rapidely (2-4 h) absorbed after oral administration on unfed animals and its bioavailability is between 60% and 80%.
This bioavailability can be reduced in the presence of food in the stomach as oxytetracycline leads to the formation of insoluble chelates with divalent or trivalent cations (Mg, Fe, Al, Ca).

In pigs, the influence of food is negligible on the bioavailability of oxytetracycline which is less than 5%.

The oxytetracycline binds variably to plasma proteins according to the species (20-40%). Its distribution is large. The oxytetracycline diffuses throughout the body, the highest concentrations have been found in the kidneys, liver, spleen and lungs. The oxytetracycline crosses the placental barrier.

Oxytetracycline is excreted unchanged mainly via urine. It is also excreted via bile but a high proportion of oxytetracycline is reabsorbed by the small intestine (enterohepatic cycle).

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Citric acid, anhydrous.

6.2. Incompatibilities

In 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:

- Jar of 1 kg: 2 years.
- Bags of 5 and 10 kg: 18 months

Shelf life after first opening: 6 months.
Shelf life after dissolution in drinking water: 24 hours

6.4. Special precautions for storage

Bags of 5 and 10 kg: Do not store above 25 ° C.

6.5. Nature and composition of immediate packaging

Jar made of high density polyethylene
Screw cap made of low density polyethylene / aluminium
Cardboard operculum / polypropylene
Bag made of low density polyethylene / paper / paper

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

7. MARKETING AUTHORISATION HOLDER

HUVEPHARMA SA
34 RUE JEAN MONNET
ZI D'ETRICHE
SEGRE
49500 SEGRE-EN-ANJOU BLEU
FRANCE

8. MARKETING AUTHORISATION NUMBER (IN FRANCE)

FR/V/2427215 3/2014

Jar of 1 kg
Bag of 5 kg
Bag of 10 kg

Not all pack sizes may be marketed.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION IN FRANCE

10/09/2014

10. DATE OF REVISION OF THE TEXT IN FRANCE

10/09/2014