

HYPERSOL

Combined Labeling project and package leaflet project according the QRD template

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

5 kg bucket and 5 kg bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HYPERSOL, 500 mg/g powder for use in drinking water

2. COMPOSITION

Each g of product contains:

Active substance

Oxytetracycline (as hydrochloride)....500 mg

3. PACKAGE SIZE

5 kg

4. TARGET SPECIES

Chickens (broilers, breeding hens) and pigs.

5. INDICATIONS FOR USE

Indications for use

-Treatment and metaphylaxis at the group level of septicaemia, of respiratory infections and of digestive infections caused by bacteria sensitive to oxytetracycline.

The presence of disease in the group should be established before the veterinary medicinal product is used.

6. CONTRAINDICATIONS

Contraindications

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

Do not use in cases of known tetracycline resistance.

7. SPECIAL WARNINGS

Special warnings

Special precautions for safe use in the target species:

This powder should be dissolved in water, before use.

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If not possible, therapy should be based on local epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies. Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the oxytetracycline and may decrease the effectiveness of treatment with tetracyclines, due to the potential for cross-resistance.

Prolonged or repeated use of oxytetracycline should be avoided as these practises can enforce development and spread of the bacterial resistance. This is particularly likely in enterobacteria and *Salmonella* spp many of which are already resistant.

As eradication of the target pathogens may not be achieved, medication should be combined with good management practises, e.g. good hygiene, proper ventilation, no overstocking.

Extensive resistance to oxytetracycline has been recognised in porcine and poultry isolates of strains from *E. Coli*, *Salmonella* spp., *Campylobacter* spp., and *Enterococcus* spp. The veterinary medicinal product should only be used where culture and sensitivity testing have demonstrated that it is likely to be effective.

Sick animals may have a reduced appetite and an altered drinking pattern and should, if necessary, be medicated parenterally.

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 veterinary medicinal 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 veterinary medicinal product.

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

Pregnancy and lactation:

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. Product safety has not been evaluated during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interactions with other medicinal products and other forms of interaction:

Divalent or trivalent cations (Mg, Fe, Al, Ca) may chelate with tetracyclines. The tetracyclines 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.

Major Incompatibilities:

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

8. ADVERSE EVENTS

Adverse events

Chickens and pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Allergic and photosensitivity reactions ¹
Undetermined frequency (cannot be estimated from the available data)	Digestive tract disorder ¹

¹Common effect for all tetracyclines.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system {national system details}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

In drinking water use.

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 mean daily water consumption.

The duration of treatment is 3 to 5 days, for both chickens and pigs.

Dosing is presented in the following table:

Species	Expressed in mg of oxytetracycline / kg of bodyweight / day	Expressed in mg of ORAL POWDER / 10 kg of bodyweight / day	Estimated water consumption (L / kg of bodyweight)	Expressed in mg of ORAL POWDER / L of drinking water
Pigs	20 mg	400 mg of ORAL POWDER	1 L / 10 kg of bodyweight	400 mg of ORAL POWDER
Chickens	20 mg	400 mg of ORAL POWDER	1 L / 5 kg of bodyweight	200 mg of ORAL POWDER

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

$$\frac{\text{mg of veterinary medicinal product}}{\text{/ kg body weight / day}} \times \text{average body weight (kg) of animals to be treated} = \text{mg veterinary medicinal product per litre of drinking water}$$

Mean daily water consumption (L/ animal)

To ensure a correct dosage, body weight should be determined as accurately as possible.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

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 veterinary medicinal 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.

11. WITHDRAWAL PERIODS

Withdrawal periods

Pigs:

Meat and offal: 7 days

Chickens:

Meat and offal: 7 days

Eggs: not for use in laying birds producing eggs intended for human consumption

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out the sight and reach of children.

No special storage conditions are required.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. These measures help to protect the environment. Ask your veterinary surgeon how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 41623/3001

Pack sizes

Jar of 1 kg

Bucket of 1 bag of 5 kg

Bags of 5 kg and 10 kg

Not all pack sizes may be marketed.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk

17. CONTACT DETAILS

Contact details

Marketing authorization holder and manufacturer responsible for batch release and contact detail to report suspected adverse reactions:

Huvepharma SA
34 Rue Jean Monnet
ZI d'etriché
Segré
49500 Segré-en-Anjou Bleu
France
Tel : +33 (0)2 41 92 11 11
E-mail : info.france@huvepharma.com

Contact details to report suspected adverse reactions:

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp 4{mm/yyyy}

Shelf life after first opening the immediate packaging:

- 5 kg bucket: 6 months
- 5 kg bag: 3 months

Shelf life after dissolution in drinking water according to the directions: 24 hours

21. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

10 kg bag

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HYPER SOL, 500 mg/g powder for use in drinking water

2. COMPOSITION

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Active substance

Oxytetracycline (as hydrochloride).....500 mg

3. PACKAGE SIZE

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12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

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Do not store at a temperature higher than 25°C.

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Special precautions for disposal

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34 Rue Jean Monnet
ZI d'etriché
Segré
49500 Segré-en-Anjou Bleu
France
Tel : +33 (0)2 41 92 11 11
E-mail : info.france@huvepharma.com

Contact details to report suspected adverse reactions:

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Lot {number}

Gavin Hall

Approved: 15 May 2025