HYPERSOL

Combined Labeling project and package leaflet project according the QRD template

1. NAME AND ADRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IF DIFFERENT

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France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Active substance: oxytetracycline (as hydrochloride)

3. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 g of product contains:

Active substance
Oxytetracycline (as hydrochloride)…….500 mg

4. PACK SIZE

1 kg (or 5 kg or 10 kg)

5. PHARMACEUTICAL FORM

Powder for use in drinking water

6. INDICATION

Chickens (broilers, breeding hens) and pigs.

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 herd/group should be established before the product is used.

7. CONTRAINDICATION

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.

8. ADVERSE REACTIONS

As for all other tetracyclines, side effects such as gastro-intestinal disorder and less frequently, allergic and photosensitivity reactions are very rare (less than 1 animal in 10,000 animals treated, including isolated reports) according to phamacovigilance data.

If you notice any side effects, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon.

9. TARGET SPECIES

Chickens (Broilers, breeding hens) and pigs.

10. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Oral 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 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:

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

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

11. 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 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.

12. WITHDRAWAL PERIOD

Meat and offal: 7 days
Eggs: Do not use for birds laying eggs for human consumption

13. SPECIAL WARNINGS

- Special precautions for use in animals

This powder should be dissolved in water, before use.
Use of the product should be based on susceptibility testing of bacteria isolates from the animal. If not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Use of the 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.
The 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 form *E. Coli*, *Salmonella* spp., *Campylobacter* spp., and *Enterococcus* spp. The 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 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.

- Use during 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

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.

- Overdose

None known.

- Incompatibilities

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

14. EXPIRY DATE

Used before: month/year
Shelf life after first opening the container:
- 1 kg jar and 5 kg bucket: 6 months
- 5 kg and 10 kg bags: 3 months

Shelf life after dilution in drinking water: 24 hours

15. SPECIAL STORAGE CONDITIONS

For 1 kg jar and 5 kg bucket: No special storage conditions are required.
For 5 kg and 10 kg bags: Do not store at a temperature higher than 25°C.

16. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

17. THE WORD "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

For animal treatment only.
To be supplied only on veterinary prescription.

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

Keep out of the reach and sight of children.

19. MARKETING AUTHORISATION NUMBER

Vm 41623/5001

20. MANUFACTURER'S BATCH NUMBER

Batch number:

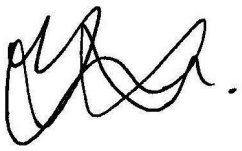
21. DATE ON WHICH PACKAGE LEAFLET WAS LAST APPROVED

March 2020

22. OTHER INFORMATION

1 kg jar
Bucket of a 5 kg bag
5 k bag
10 kg bag

Not all pack size may be marketed.



Approved: 26 March 2020