PARTICULARS TO APPEAR ON THE IMMEDIATE/OUTER PACKAGE {1 KG JAR}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 g of product contains:

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

3. PACKAGE SIZE

1 kg

4. TARGET SPECIES

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Powder for use in drinking water.

7. WITHDRAWAL PERIODS

Withdrawal period

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.

8. EXPIRY DATE

EXP

Exp: month/year
Shelf life after first opening the immediate packaging:
- 1 kg jar and 5 kg bucket: 6 months
- 5 kg and 10 kg bags: 3 months

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

9. SPECIAL STORAGE PRECAUTIONS

Keep out the sight and reach of children.

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.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma SA
34 Rue Jean Monnet
ZI d'Etriche
Segre
49500 Segre-en-Anjou Bleu
France

14. MARKETING AUTHORISATION NUMBERS

Vm 41623/5001

15. BATCH NUMBER

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V ('To be supplied only on veterinary prescription')

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HYPERSOL 500 mg/g Powder for use in Drinking water

2. COMPOSITION

1 g of product contains:

Active substance:
Oxytetracycline (as hydrochloride) 500 mg

Yellow powder

3. TARGET SPECIES

Chickens (broilers, breeding hens) and pigs.

4. INDICATIONS FOR USE

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

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

5. 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.

6. 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 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 practices, 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 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 veterinary 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 passes the placental barrier, resulting in staining of teeth and slow foetal growth.
Tetracyclines are found in breast milk.

Use only according to the benefit/risk assessment by the responsible veterinarian.

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.

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

7. ADVERSE EVENTS

Chickens and pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Allergic and photosensitivity reactions[1]
Undetermined frequency	Digestive tract disorder[1]

[1]Common 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 in this package leaflet, 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 at the end of this leaflet, or via your national reporting system: {national system details}.

8. DOSAGE FOR EACH SPECIES, ROUTES 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	1 L / 10 kg of	400 mg of

		POWDER	bodyweight	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:

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

9. ADVICE ON CORRECT ADMINISTRATION

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

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.

10. 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months
Shelf life after dissolution in drinking water according to directions: 24 hours

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
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 should help to protect the environment
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.'

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V (To be supplied only on veterinary prescription).

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 41623/5001

Not all pack sizes may be marketed.

15. 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.

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:
Huvepharma SA
34 Rue Jean Monnet
ZI d'Etriche
Segre
49500 Segre-en-Anjou Bleu
France
Tel : +33 (0)2 41 92 11 11
E-mail : info.france@huvepharma.com

Local representative and contact details to report suspected adverse reactions:
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium
+32 3 288 18 49
pharmacovigilance@huvepharma.com

17. OTHER INFORMATION

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, I.e. Combined label and package leaflet {NATURE/TYPE}

[This template should only be used when all printed information is directly visible on the immediate container and cannot be used if a fold-out or concertina format is proposed.]

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
10 kg

4. TARGET SPECIES

Chickens (broilers, breeding hens) and pigs.

5. 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

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 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 form *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 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.

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

8. ADVERSE REACTIONS

Chickens and pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Allergic and photosensitivity reactions[1]
Undetermined frequency	Digestive tract disorder[1]

[1]Common 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 in this package leaflet, 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 at the end of this label, or via your national reporting system:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH 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:

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

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

10. 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.

For 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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
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 should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V (To be supplied only on veterinary prescription).

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 41623/5001

Pack sizes
1 kg jar
Bucket of a 5 kg bag

5 k bag
10 kg bag

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

Marketing authorization holder and manufacturer responsible for batch release
Huvepharma SA
34 Rue Jean Monnet
ZI d'Etriche
Segre
49500 Segre-en-Anjou Bleu
France
Tel : +33 (0)2 41 92 11 11
E-mail : info.france@huvepharma.com

Local representative and contact details to report suspected adverse reactions:
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium
~~or~~ +32 3 288 18 49
pharmacovigilance@huvepharma.com

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

20. EXPIRY DATE

Do not use this veterinary medicinal product after the expiry date which is stated on the bag after EXP. The expiry date refers to the last day of that month.

21. BATCH NUMBER

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

Keep out of the sight and reach of children.

Gavin Hall

Approved: 26 February 2025