

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {BAG}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxx-Sol 500 mg/g powder for use in drinking water/milk replacer

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:
433 mg doxycycline equivalent to 500 mg doxycycline hyclate

3. PACKAGE SIZE

1 kg
5 kg

4. TARGET SPECIES

Cattle (pre-ruminant), pigs, chickens (for reproduction, broilers and pullets)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Powder for use in drinking water/milk replacer

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal:
Cattle (pre-ruminant): 7 days
Pigs: 8 days
Chickens (for reproduction, broilers and pullets): 5 days

Not for use in birds producing or intended to produce eggs for human consumption.

8. EXPIRY DATE

Exp{mm/yyyy}

Shelf life after first opening of the immediate packaging: 3 months.

Shelf life after dissolution in drinking water: 24 hours.

Shelf life after dissolution in milk replacer: 4 hours.

Once opened, use by:

9. SPECIAL STORAGE PRECAUTIONS

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 NV

14. MARKETING AUTHORISATION NUMBER

Vm 30282/4022

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Doxx-Sol 500 mg/g powder for use in drinking water/milk replacer for pre-ruminant calves, pigs and chickens.

2. Composition

Each gram contains:

Active substance:

433 mg doxycycline equivalent to 500 mg doxycycline hyclate

Yellowish powder.

3. Target species

Cattle (pre-ruminant), pigs, chickens (for reproduction, broilers and pullets)

4. Indications for use

Treatment of the following specified infectious diseases of the respiratory tract and the alimentary tract caused by micro-organisms susceptible to doxycycline.

Cattle (Pre-ruminant)

- Bronchopneumonia and pleuropneumonia caused by *Pasteurella spp.*, *Streptococcus spp.*, *Trueperella pyogenes*, *Histophilus somni* and *Mycoplasma spp.*

Pigs:

- Atrophic rhinitis caused by *Pasteurella multocida* and *Bordetella bronchiseptica*;
- Bronchopneumonia caused by *Pasteurella multocida*, *Streptococcus suis* and *Mycoplasma hyorhinis*;
- Pleuropneumonia caused by *Actinobacillus pleuropneumoniae*.

Chickens (for reproduction, broilers and pullets):

- Infections of the respiratory tract caused by *Mycoplasma spp.*, *Escherichia coli*, *Haemophilus paragallinarum* and *Bordetella avium*;
- Enteritis caused by *Clostridium perfringens* and *Clostridium colinum*.

5. Contraindications

Do not use in cases of hypersensitivity to tetracyclines or to any of the excipients.
Do not use in animals with serious liver or kidney deficiency.
Do not use when tetracycline resistance has been detected in the herd/flock due to the potential for cross resistance
Do not use in ruminating cattle.

6. Special warnings

Special precautions for safe use in the target species:

A high resistance rate of *E. coli*, isolated from chickens, against tetracyclines has been documented. Resistance to tetracyclines has also been reported in pig respiratory pathogens (*A. pleuropneumoniae*, *S. suis*) and calf pathogens (*Pasteurella* spp.) in some EU countries.

Use of the product should be based on identification and susceptibility testing of the target pathogens. If it is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target bacteria at farm level, or at local/regional level.

Use of the product deviating from the instructions given in the package leaflet may increase the prevalence of bacteria resistant to doxycycline and may decrease the effectiveness of treatment.

Official, national and regional antimicrobial policies should be taken into account when the product is used.

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

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

Take measures to avoid producing dust when incorporating the veterinary medicinal product into water. This veterinary medicinal product may cause contact dermatitis and/or hypersensitivity reactions if contact is made with the skin or eyes (powder and solution), or if the powder is inhaled.

People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product. Personal protective equipment consisting of impermeable gloves (e.g. rubber or latex) and an appropriate dust mask (e.g. disposable half-mask respirator conforming to European Standard EN149) should be worn when handling the veterinary medicinal product. Do not smoke, eat or drink while handling the product.

In case of accidental eye or skin contact, rinse the affected area with large amounts of clean water and if irritation occurs, seek medical advice immediately and show the package leaflet or the label to the physician.. Wash hands and contaminated skin immediately after handling the product.

If you develop symptoms following exposure such as skin rash, seek medical advice immediately and show and show the package leaflet or 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

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established in pregnant or lactating sows.

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects

Due to depositing of doxycycline in young bone tissue, use of the product should be limited during pregnancy and lactation.

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

Interaction with other medicinal products and other forms of interaction:

Do not use in conjunction with bactericidal antibiotics, such as penicillins and cephalosporins.

Do not administer concurrently with feed overloaded with polyvalent cations such as Ca^{2+} , Mg^{2+} , Zn^{2+} and Fe^{3+} because the formation of doxycycline complexes with these cations is possible. Do not administer together with antacids, kaolin and iron preparations. It is advised that the interval between administration of the veterinary medicinal product and administration of products containing polyvalent cations should be 1-2 hours because the latter limit the absorption of doxycycline.

Doxycycline increases the action of anticoagulants.

Overdose:

In calves acute, sometimes fatal myocardial degeneration can occur following single or multiple dosages. Since mostly this is caused by overdosage, it is important to measure the dosage accurately.

If suspected toxic reactions do occur due to extreme overdose, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.

Major incompatibilities:

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water or liquid feed containing biocidal products, feed additives or other substances used in drinking water

7. Adverse events

Cattle (pre-ruminant), pigs, chickens (for reproduction, broilers, and pullets).

Rare (1 to 10 animals / 10 000 animals)	Allergic reaction* Photosensitivity* (sensitivity to light)
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*If suspected adverse reactions occur, treatment should be discontinued

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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Oral use

Administration through the milk-replacer or the drinking water.

Cattle (Pre-ruminant):

for use in milk replacer

10 mg doxycycline hyclate (corresponding to 20 mg of the veterinary medicinal product) /kg body weight / day, divided over 2 administrations, for 3-5 consecutive days.

Pigs:

for use in drinking water

10 mg doxycycline hyclate (corresponding to 20 mg of the veterinary medicinal product) /kg body weight / day, for 3-5 consecutive days.

Chickens (broilers, breeders, replacement pullets):

for use in drinking water

25 mg doxycycline hyclate (corresponding to 50 mg of the veterinary medicinal product)/kg body weight / day, for 3-5 consecutive days.

9. Advice on correct administration

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

In drinking water:

Clear solution when dissolved in water

Based on the recommended dose, and the number and weight of the animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

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

The intake of medicated water is depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of doxycycline may need to be adjusted accordingly. The use of suitably calibrated measuring equipment is recommended.

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.

It is recommended to prepare a concentrated pre-solution - not exceeding 100 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. The water should be stirred until full dissolution of the product is obtained. Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. No other source of drinking water should be available during the medication period. At the end of treatment period the water supply should be cleaned adequately to avoid the uptake of remaining quantities in sub-therapeutic doses.

The solubility of doxycycline decreases at higher pH. Therefore, the product should not be used in hard alkaline water since precipitation might occur depending on the product concentration. Delayed precipitation might also occur.

In milk replacer:

The veterinary medicinal product must first be dissolved in water before adding the milk powder. The medicated milk replacer should be used immediately and should be freshly prepared after 4 hours at the latest.

10. Withdrawal periods

Meat and offal:

Cattle (pre-ruminant): 7 days

Pigs: 8 days

Chickens (for reproduction, broilers, pullets): 5 days

Not for use in birds producing or intended to produce eggs 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 expiry date which is stated on the label after Exp. The expiry date refers to the last day of the month

Shelf life after first opening the immediate packaging: 3 months.

Shelf life after dissolution in drinking water: 24 hours.

Shelf life after dissolution in milk replacer: 4 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. 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

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 30282/4022

Bag size 1 kg, 5 kg.

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:

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

Manufacturer responsible for batch release

Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

Local representatives and contact details to report suspected adverse reactions:

Huvepharma Ltd
Bath House
6-8 Bath Street
Bristol
United Kingdom BS1 6HL
Tel: +32 3 318 36 54

pharmacovigilance@huvepharma.com

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Gavin Hall
Approved: 18 September 2025