**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 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

Doxx-Sol 500 mg/g powder for use in drinking water/milk replacer for cattle, pigs and chickens (Poland )

Doxx-Sol 433 mg/g powder for use in drinking water/milk replacer for pre-ruminant calves, pigs and chickens (France)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

**Active substance:**
433 mg doxycycline equivalent to 500 mg doxycycline hyclate

**Excipients:**

| **Qualitative composition of excipients and other constituents** |
|---|
| Citric acid, anhydrous |
| Lactose monohydrate |

Yellowish powder.

## 3. CLINICAL INFORMATION

### 3.1 Target species

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

### 3.2 Indications for use for each target species

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*.

### 3.3 Contraindications

Do not use in cases of hypersensitivity to tetracyclinesor 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.

### 3.4 Special warnings

None.

### 3.5 Special precautions for use

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 veterinary medicinal 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 veterinary medicinal product deviating from the instructions given in the SPC 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 veterinary medicinal 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 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 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 the package leaflet or label to the physician. Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

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

| | |
|---|---|
| Rare<br>(1 to 10 animals / 10 000 animals treated): | Allergic reaction*<br>Photosensitivity* |

*If suspected adverse events occur, treatment should be discontinued.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation. 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 veterinary medicinal product should be limited during pregnancy and lactation.

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

### 3.8 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.

### 3.9 Administration routes and dosage

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 (for reproduction, broilers and 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.

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:

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

The intake of medicated water 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 of the veterinary medicical 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 veterinary medicinal 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 veterinary medicinal product should not be used in hard alkaline water since precipitation might occur depending on the veterinary medicinal 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 4hours at the latest.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 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.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code:
QJ01AA02

### 4.2 Pharmacodynamics

Doxycycline is a broad spectrum antibiotic. It inhibits bacterial protein synthesis intracellularly by binding on the 30-S ribosome subunits. This interferes with binding of amino acetyl-tRNA to the acceptor site on the mRNA ribosome complex and prevents coupling of amino acids to the elongating peptide chains.

Doxycycline is a broad-spectrum antibiotic, active against a large number of Gram-positive and Gram-negative, aerobic and anaerobic micro-organisms and *Mycoplasmata*.

Four resistance mechanisms acquired by microorganisms against tetracyclines in general have been reported: decreased accumulation of tetracyclines (decreased permeability of the bacterial cell wall and active efflux), protein protection of the bacterial ribosome, enzymatic inactivation of the antibiotic and rRNA mutations (preventing the tetracycline binding to ribosome). Tetracycline resistance is usually acquired by means of plasmids or other mobile elements (e.g. conjugative transposons). Cross resistance between tetracyclines has also been described. Due to the greater liposolubility and greater facility to pass through cell membranes (in comparison to tetracycline), doxycycline retains a certain degree of efficacy against microorganisms with acquired resistance to tetracyclines.

### 4.3 Pharmacokinetics

Doxycycline is quickly and almost completely absorbed from the intestine. The presence of food in the intestine has no effect on the actual absorption of doxycycline. The distribution of doxycycline and penetration of doxycycline throughout most body tissues is good.
Following absorption, tetracyclines are hardly metabolized. In contrast to the other tetracyclines, doxycycline is mainly excreted via the feces.

*Cattle (pre-ruminant)*
After a dosage of 10 mg/kg body weight /day during 5 days, an elimination halftime varying between 15 and 28 hours was found. The doxycycline plasma level reached an average of 2.2 to 2.5 µg/ml.

*Pigs*
In pigs, no accumulation of doxycycline in plasma was found after treatment via the drinking water. Mean plasma values of 0.44 ± 0.12 µg/ml after 3 days of medication with an average dose of 10 mg/kg body weight were found.

*Chickens (for reproduction, broilers and pullets)*
Steady state plasma concentrations of 2.05 ± 0.47 µg/ml were reached within 6 hours after start of the medication and varied between 1.28 and 2.18 µg/ml with a dosage of 25 mg/kg body weight during 5 days.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 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 ..

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
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.

### 5.3 Special precautions for storage

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

### 5.4 Nature and composition of immediate packaging

Bag of 1 kg or 5 kg formed from polyethylene/aluminium/polyethylene terephtalate laminate.

Not all pack sizes may be marketed.

### 5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

## 7. MARKETING AUTHORISATION NUMBER(S)

## 8. DATE OF FIRST AUTHORISATION

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

**ANNEX II**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**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

Oral use, administration through the milk-replacer or the drinking water.

## 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.

## 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 NUMBERS

## 15. BATCH NUMBER

Lot {number}

# B. 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 administer to animals with serious liver or kidney insufficiency.
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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 the package leaflet or 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 during pregnancy or lactation. 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 veterinary medicinal product should be limited 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:
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<br>(1 to 10 animals / 10 000 animals treated): | Allergic reaction*<br>Photosensitivity* (sensitivity to light) |

*If suspected adverse events 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 its local representative using the contact details at the end of this leaflet, or via your national reporting system:

## 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 (for reproduction, broilers and 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

In drinking water:
Clear solution when dissolved in water.
To ensure a correct dosage, body weight should be determined as accurately as possible.

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 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 of the 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. The water should be stirred until full dissolution of the veterinary medicinal 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 veterinary medicinal 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 and 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 or household waste.

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 system. 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

Bag of 1 kg or 5 kg formed from polyethylene/aluminium/polyethylene terephtalate laminate.

Not all pack sizes may be marketed.

## 15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## 16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium
+32 3 288 18 49
pharmacovigilance@huvepharma.com

Manufacturer responsible for batch release
Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

<Local representatives and <contact details to report suspected adverse events>>
<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder>.

## <17. Other information>