

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DOXIPULVIS 500 MG/G POWDER FOR USE IN DRINKING WATER / MILK

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

### Active substances:

Doxycycline 500.0 mg  
(As doxycycline hyclate 577.1 mg)

### Excipients:

Qualitative composition of excipients and other constituents
Citric acid
Strawberry flavouring

Yellow fine powder

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle (pre-ruminant calves), pigs, chickens (broilers, for reproduction) and turkeys (for meat production, for reproduction)

### 3.2 Indications for use, for each target species

In calves:

- Treatment and metaphylaxis of respiratory and digestive infections caused by micro-organisms susceptible to doxycycline.

In pigs:

- Treatment and metaphylaxis of respiratory infections caused by micro-organisms susceptible to doxycycline.

In chickens and turkey:

- Treatment and metaphylaxis of respiratory infections due to micro-organisms susceptible to doxycycline.

In the case of metaphylaxis, the presence of the disease in the group must be established before the product is used.

### **3.3 Contraindications**

Do not use in cases of hypersensitivity to the active substance, to other tetracyclines or to any of the excipients.

Do not use when tetracycline resistance has been detected in the herd/flock due to the potential for cross resistance.

Do not use in animals with renal or hepatic disorders.

Do not use in ruminating cattle.

### **3.4 Special warnings**

The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of drinking water, calves and pigs should be treated parenterally.

Use of the 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 with other tetracyclines due to the potential for cross-resistance.

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

Cross-resistance has been shown between doxycycline and other tetracyclines. Use of doxycycline should be carefully considered when susceptibility testing has shown resistance to tetracyclines because its effectiveness may be reduced.

A high resistance rate for *Escherichia coli* isolated from chickens against tetracyclines has been documented. Therefore, the product should be used for the treatment of infections caused by *E. coli* only after susceptibility testing has been carried out. Resistance to tetracyclines has also been reported in pig respiratory pathogens (*Actinobacillus pleuropneumoniae*, *Streptococcus suis*) and calf pathogens (*Pasteurella* spp.) in some EU countries.

### **3.5 Special precautions for use**

#### Special precautions for safe use in the target species:

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

Use of the product should be in accordance with official, national and regional antimicrobial policies.

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

- This 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.
- Take measures to avoid producing dust when incorporating the product into water. Avoid direct contact with skin and eyes when handling the product to prevent sensitisation and contact dermatitis.
- People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.
- During preparation and administration of the medicated drinking water, skin contact with the product and inhalation of dust particles should be avoided. Wear impermeable gloves (e.g. rubber or latex) and an appropriate dust mask (e.g. disposable half – mask respirator conforming to European Standard EN149 or a non – disposable respirator to European Standard EN140 with a filter to EN143) when applying the product.
- In the event of eye or skin contact, rinse the affected area with large amounts of clean water and if irritation occurs, seek medical attention.
- Wash hands and contaminated skin immediately after handling the product.

If you develop symptoms following exposure such as skin rash, you should seek medical advice and show this warning 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 calves), pigs, chickens (broilers, for reproduction) and turkeys (for meat production, for reproduction):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorder* Allergic reaction* Photosensitization*
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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 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 also the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Doxycycline showed no evidence of teratogenic or embryotoxic effects in laboratory animals. In mammals, doxycycline crosses the placental barrier. Due to a lower affinity for calcium, doxycycline results in less staining of teeth compared to tetracycline. Doxycycline is found in breast milk.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. In pregnant and lactating animals use only in accordance to the benefit/risk assessment by the responsible veterinarian.

### 3.8 Interaction with other medicinal products and other forms of interaction

Divalent or trivalent cations (Mg, Fe, Al, Ca) can chelate tetracyclines. Tetracyclines should not be administered with antacids, gels based on aluminum, preparations based on vitamins or minerals, since insoluble complexes are formed, which reduces the absorption of the antibiotic. Do not use in conjunction with bactericidal antibiotics, such as penicillins or cephalosporins. Doxycycline increases the action of anticoagulants.

### 3.9 Administration routes and dosage

Oral use.

To be administered orally in milk replacer, drinking water or liquid feed.

#### Calves, pigs:

10 mg of doxycycline per kg of body weight per day (equivalent to 11.54 mg of doxycycline hyclate/kg bw /day) by oral route, during 3 to 5 days, or 0.2 g of powder per 10 kg of body weight per day, during 3-5 consecutive days, to be dissolved in drinking water, milk or liquid feed; to be adjusted according to actual feed intake of the animals, in order to meet the weight dosage.

#### Chickens and turkeys:

10 mg of doxycycline per kg of body weight per day (equivalent to 11.54 mg of doxycycline hyclate/kg bw /day), equivalent to 0.02 g of soluble powder per kg of body weight during 3 to 5 consecutive days, to be dissolved in drinking water.

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

$$\frac{0.02 \text{ g of powder per kg of body weight per day} \times \text{body weight (kg) of the animals to be treated}}{\text{Average water intake per animal (litres)}} = \dots \text{ g of powder per litre of drinking water}$$

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

The intake of medicated feed or 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 weighing equipment for the administration of the calculated amount of product is recommended.

The daily amount of powder should be added to the drinking water so that the drug is consumed in 24 hours divided in two administrations. Drinking water containing the drug substance has to be freshly prepared every 12 hours. It is recommended to prepare a concentrated solution (approximately 10 g of product per litre of water) which can be diluted later, if necessary, to the therapeutic concentration. It is also possible to distribute the concentrated solution using a metering pump.

The product should not be prepared at a concentration below 0.1 g of powder/L of hard water/milk and at pH above 8.2.

The solubility of the product has been tested at the maximum concentration of 400 g/L.

The medicated water should be the only source of drinking water, throughout the treatment period. Water uptake should be monitored at frequent intervals during medication.

Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. The medicated water must not be prepared or stored in a metal container. After the end of the medication period, the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

The temperature of the milk replacer should not be above 38°C prior to the introduction of the finished product.

The milk replacer should be prepared no more than one hour prior to the addition of the product and the medicated milk replacer should be used immediately.

When administering in liquid feed, first dissolve the product in water and then add feed. The preparation should be used immediately. Care should be taken that the intended dose will be completely ingested.

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

Not described. If suspected toxic reactions occur, the medication should be discontinued and appropriate symptomatic treatment should be initiated.

### **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 (Calves): 14 days
- Pigs: 6 days
- Chicken: 7 days
- Turkeys: 12 days

Not for use in birds producing eggs for human consumption.

Do not use within 4 weeks before the start of the laying period.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code:

QJ01AA02

### 4.2 Pharmacodynamics

Doxycycline binds reversibly to receptors of ribosomal fraction 30S, which leads to a blockade of the aminoacyl-tRNA binding to the corresponding site of the complex ribosome-RNA messenger. This results in inhibition of protein synthesis and therefore stops the growth of the bacterial culture. Doxycycline has a predominantly bacteriostatic activity.

Doxycycline is a broad spectrum antibiotic. It is primarily active against Gram positive and negative microorganisms, aerobic and anaerobic, and against *Mycoplasma*, *Chlamydia* and *Rickettsiae*.

The bacteriostatic activity of doxycycline involves penetration of the substance into the bacterial cell. The penetration of doxycycline takes place by both active and passive diffusion.

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 is common but depends on the mechanism conferring resistance. Due to the greater liposolubility and greater ability to pass through cell membranes (in comparison to tetracycline), doxycycline retains a certain degree of efficacy against microorganisms with acquired resistance to tetracyclines via efflux pumps. However, resistance mediated by ribosomal protection proteins confer cross – resistance to doxycycline.

The following Minimal Inhibitory Concentrations (MIC) have been determined for doxycycline in European isolates target pathogens. Breakpoints Sensitive  $\leq 4\mu\text{g/ml}$  ( CLSI 2018).

Species	Bacterial pathogen	Number of isolates	Year of isolation	MIC <sub>50</sub> (µg/ml)	MIC <sub>90</sub> (µg/ml)
Chickens /Turkeys	<i>Mycoplasma spp.</i>	154	2012 - 2017	0.5	1
Pigs	<i>A.pleuropneumoniae</i>	162	2017 – 2019	1	4
	<i>P. multocida</i>	130	2017 – 2019	0.5	4
Cattle	<i>P. multocida</i>	149	2018	0.25	1
	<i>M. haemolytica</i>	82	2018	0.5	1

### 4.3 Pharmacokinetics

Doxycycline is quickly (2-3 hours) absorbed after oral administration and its bioavailability in most species is around 70%.

Doxycycline is highly bound to plasma proteins (about 90%). Highly fat soluble in comparison to first generation tetracyclines, doxycycline is widely distributed throughout the body. The highest concentrations were found in the lungs, kidneys, liver and spleen. Doxycycline crosses the placental barrier.

Doxycycline is excreted by the biliary route, but a large proportion is reabsorbed by the small intestine (enterohepatic cycle). 40% of doxycycline is metabolized and excreted in the feces, mainly as inactive conjugated metabolites.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

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

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: 2 years.

Shelf life after first opening the immediate packaging: 1 month.

Shelf life after dilution in drinking water according to directions: 12 hours.

Shelf life after dilution in milk replacer according to directions: 1 hour.

Shelf life after dilution in liquid feed according to directions: use immediately.

### **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**

Low-density polyethylene/ Aluminium/ Polypropylene bags.

Pack sizes:

200 g

1 kg

Not all pack sizes may be marketed.

### **5.5 Special precautions for the disposal of unused veterinary medicinal product 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**

S.P. VETERINARIA, S.A.

**7. MARKETING AUTHORISATION NUMBER(S)**

FR: FR/V/3693359 4/2016

HU: 3818/X/16 NÉBIH ÁTI

UK: Vm 36967/3001

IE: VPA10790/008/001

MT: VMA49

PL: 2641

RO: 220018

IT: 104912

PT: 1038/01/16DFVPT

EL: 165/11-01-2022/K-0215401

CY: CY00584V

DE: 402241.00.00

ES: 3493 ESP

**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: {DD month YYYY}.

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

{DD/YYYY}

**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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Label for 200 g container and 1 Kg container**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

DOXIPULVIS 500 MG/G POWDER FOR USE IN DRINKING WATER / MILK

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each gram contains:

Doxycycline 500.0 mg  
(As doxycycline hyclate 577.1 mg)

**3. PACKAGE SIZE**

200 g  
1 Kg

**4. TARGET SPECIES**

Cattle (pre-ruminant calves), pigs, chickens (broilers, for reproduction) and turkeys (for meat production, for reproduction)

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Oral use.  
To be administered orally in milk replacer, drinking water or liquid feed.

**7. WITHDRAWAL PERIODS**

Withdrawal periods:

Meat and offal:

- Cattle (Calves): 14 days.
- Pigs: 6 days.
- Chicken: 7 days.
- Turkeys: 12 days.

Not for use in birds producing eggs for human consumption.  
Do not use within 4 weeks before the start of the laying period.

## **8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened, use by 1 month..

Once diluted in drinking water, used by 12 hours.

Once diluted, in milk replacer used by 1 hour.

Once diluted, in liquid feed use immediately.

## **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**

S.P. VETERINARIA, S.A.

## **14. MARKETING AUTHORISATION NUMERS**

FR: FR/V/3693359 4/2016

HU: 3818/X/16 NÉBIH ÁTI

UK: Vm 36967/3001

IE: VPA10790/008/001

MT: VMA49

PL: 2641

RO: 220018

IT: 104912

PT: 1038/01/16DFVPT

EL: 165/11-01-2022/K-0215401

CY: CY00584V

DE: 402241.00.00

ES: 3493 ESP

## **15. BATCH NUMBER**

Lot {number}

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

DOXIPULVIS 500 MG/G POWDER FOR USE IN DRINKING WATER / MILK

### 2. Composition

Each gram contains:

#### Active substances:

Doxycycline (hyclate) 500.0 mg  
(As doxycycline hyclate 577.1 mg)

Yellow fine powder

### 3. Target species

Cattle (pre-ruminant calves), pigs, chickens (broilers, for reproduction) and turkeys (for meat production, for reproduction).

### 4. Indications for use

In calves:

- Treatment and metaphylaxis of respiratory and digestive infections caused by germs susceptible to doxycycline.

In pigs:

- Treatment and metaphylaxis of respiratory infections caused by germs susceptible to doxycycline.

In chickens and turkey:

- Treatment and metaphylaxis of respiratory infections due to micro-organisms susceptible to doxycycline.

In the case of metaphylaxis, the presence of the disease in the group must be established before the product is used.

### 5. Contraindications

Do not use in cases of hypersensitivity to the active substance, to other tetracyclines or to any of the excipients.

Do not use when tetracycline resistance has been detected in the herd/flock due to the potential for cross resistance.

Do not use in animals with renal or hepatic disorders.

Do not use in ruminating cattle.

### 6. Special warnings

Special warnings:

The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of drinking water, calves and pigs should be treated parenterally.

Use of the 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 with other tetracyclines due to the potential for cross-resistance.

As the eradication of target pathogens may not be achieved, medication should be combined with good animal husbandry practices such as proper sanitation, adequate ventilation, no overstocking.

Cross-resistance has been shown between doxycycline and other tetracyclines. Use of doxycycline should be carefully considered when susceptibility testing has shown resistance to tetracyclines because its effectiveness may be reduced.

A high resistance rate for *Escherichia coli*, isolated from chickens against tetracyclines has been documented. Therefore, the product should be used for the treatment of infections caused by *E. coli* only after susceptibility testing has been carried out. Resistance to tetracyclines has also been reported in pig respiratory pathogens (*Actinobacillus pleuropneumoniae*, *Streptococcus suis*) and calf pathogens (*Pasteurella* spp.) in some EU countries.

#### Special precautions for use in the target species:

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

Use of the product should be in accordance with official, national and regional antimicrobial policies.

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

- This 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.
- Take measures to avoid producing dust when incorporating the product into water. Avoid direct contact with skin and eyes when handling the product to prevent sensitisation and contact dermatitis.
- People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.
- During preparation and administration of the medicated drinking water, skin contact with the product and inhalation of dust particles should be avoided. Wear impermeable gloves (e.g. rubber or latex) and an appropriate dust mask (e.g. disposable half – mask respirator conforming to European Standard EN149 or a non – disposable respirator to European Standard EN140 with a filter to EN143) when applying the product.
- In the event of eye or skin contact, rinse the affected area with large amounts of clean water and if irritation occurs, seek medical attention.
- Wash hands and contaminated skin immediately after handling the product.

If you develop symptoms following exposure such as skin rash, you should seek medical advice and show this warning 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 :

Doxycycline showed no evidence of teratogenic or embryotoxic effects in laboratory animals.

In mammals, doxycycline crosses the placental barrier. Due to a lower affinity for calcium, doxycycline results in less staining of teeth compared to tetracycline.

Doxycycline is found in breast milk.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. In pregnant and lactating animals use only in accordance 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) can chelate tetracyclines. Tetracyclines should not be administered with antacids, gels based on aluminum, preparations based on vitamins or minerals, since insoluble complexes are formed, which reduces the absorption of the antibiotic.

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

Doxycycline increases the action of anticoagulants.

Overdose:

Not described. If suspected toxic reactions occur, the medication should be discontinued and appropriate symptomatic treatment should be initiated.

Special restrictions for use and special conditions for use:

Not applicable.

Major incompatibilities:

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

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 calves), pigs, chickens (broilers, for reproduction) and turkeys (for meat production, for reproduction):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorder* Allergic reaction* Photosensitization (abnormal skin reaction 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 its 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 use.

To be administered orally in milk replacer, drinking water or liquid feed.

Calves, pigs:

10 mg of doxycycline per kg of body weight per day (equivalent to 11.54 mg of doxycycline hyclate/kg bw /day) by oral route, during 3 to 5 days, or 0.2 g of powder per 10 kg of body weight per day, during 3-5 consecutive days, to be dissolved in drinking water, milk or liquid feed; to be adjusted according to actual feed intake of the animals, in order to meet the weight dosage.

Chickens and turkeys:

10 mg of doxycycline per kg of body weight per day (equivalent to 11.54 mg of doxycycline hyclate/kg bw /day), equivalent to 0.02 g of soluble powder per kg of body weight during 3 to 5 consecutive days, to be dissolved in drinking water.

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

$$\frac{0.02 \text{ g of powder per kg of body weight per day} \times \text{body weight (kg) of the animals to be treated}}{\text{Average water intake per animal (litres)}} = \dots \text{ g of powder per litre of drinking water}$$

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

The intake of medicated feed or 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.

**9. Advice on correct administration**

The use of suitably calibrated weighing equipment for the administration of the calculated amount of product is recommended.

The daily amount of powder should be added to the drinking water so that the drug is consumed in 24 hours divided in two administrations. Drinking water containing the drug substance has to be freshly prepared every 12 hours. It is recommended to prepare a concentrated solution (approximately 10 g of product per litre of water) which can be diluted later, if necessary, to the therapeutic concentration. It is also possible to distribute the concentrated solution using a metering pump.

The product should not be prepared at a concentration below 0.1 g of powder/L of hard water/milk and at pH above 8.2.

The solubility of the product has been tested at the maximum concentration of 400 g/L.

The medicated water should be the only source of drinking water, throughout the treatment period. Water uptake should be monitored at frequent intervals during medication.

Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. The medicated water must not be prepared or stored in a metal container. After the end of the medication period, the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

The temperature of the milk replacer should not be above 38°C prior to the introduction of the finished product.

The milk replacer should be prepared no more than one hour prior to the addition of the product and the medicated milk replacer should be used immediately.

When administering in liquid feed, first dissolve the product in water and then add feed. The preparation should be used immediately. Care should be taken that the intended dose will be completely ingested.

## **10. Withdrawal periods**

Meat and offal:

- Cattle (Calves): 14 days
- Pigs: 6 days
- Chicken: 7 days
- Turkeys: 12 days

Not for use in birds producing eggs for human consumption.

Do not use within 4 weeks before the start of the laying period.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

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

Shelf life after first opening the immediate packaging: 1 month.

Shelf life after dilution in drinking water according to directions: 12 hours.

Shelf life after dilution in milk replacer according to directions: 1 hour.

Shelf life after dilution in liquid feed according to directions: use immediately.

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.

## **12. Specific 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 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**

FR: FR/V/3693359 4/2016  
HU: 3818/X/16 NÉBIH ÁTI  
UK: Vm 36967/3001  
IE: VPA10790/008/001  
MT: VMA49  
PL: 2641  
RO: 220018  
IT: 104912  
PT: 1038/01/16DFVPT  
EL: 165/11-01-2022/K-0215401  
CY: CY00584V  
DE: 402241.00.00  
ES: 3493 ESP

#### Pack sizes:

200 g

1 kg

Not all pack sizes may be marketed.

### **15. Date on which the package leaflet was last approved**

{DD/YYYY}

### **16. Contact details**

Marketing authorisation holder <,> <and> <manufacturer responsible for batch release> <and contact details to report suspected adverse events>:

S.P. VETERINARIA, S.A.

Ctra Reus-Vinyols, km 4,1

43330 Riudoms (Spain)

Tel. +34 977 850 170

<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>**