[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxycycline Calier 500 mg/g powder for use in drinking water for chickens, turkeys and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:
Doxycycline 500 mg
(equivalent to 577 mg of doxycycline hyclate)

Excipients:

Qualitative composition of excipients and other constituents
Citric acid

Yellow powder.

3. CLINICAL INFORMATION

3.1 Target species

Chicken (broiler), Pigs (for fattening), Turkey

3.2 Indications for use for each target species

Chicken (broiler) and turkey: Prevention and treatment of Chronic Respiratory Disease (CRD) caused by *Mycoplasma gallisepticum* susceptible to doxycycline.

Pigs (fattening pigs): Prevention and treatment of clinical respiratory infection caused by sensitive strains of *Pasteurella multocida* susceptible to doxycycline.

The presence of the disease in the herd must be established before the product is used.

3.3 Contraindications

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

Do not use in animals with hepatic or renal disorders.

See section 3.7.

3.4 Special warnings

Under-dosing and/or treating for an insufficient length of time are considered to promote the development of resistance in bacteria and should be avoided.
Sick animals may have a reduced appetite and an altered drinking pattern and should, if necessary, be medicated parenterally.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Avoid administration in oxidised drinking equipment.

Due to likely variability (time, geographical) in susceptibility of bacteria to doxycycline, bacteriological sampling and susceptibility testing are recommended.

Inappropriate use of the veterinary medicinal product 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 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.

Do not use at concentrations lower than 0.23 g of powder /l in drinking water with pH higher or equal to 7.5 to avoid precipitation.

Do not add acid to the medicated drinking water.

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

This veterinary medicinal product may cause contact dermatitis and/or hypersensitivity reactions if contact is made with skin or eyes (powder and solution) or if the powder is inhaled. People with known hypersensitivity to tetracyclines should handle the veterinary medicinal product or the medicated solution with caution.

Take measures to avoid producing dust when incorporating the veterinary medicinal product into water. Avoid direct contact with skin and eyes when handling the veterinary medicinal product to prevent sensitisation and contact dermatitis.

During preparation and administration of the medicated drinking water, skin contact with the product and inhalation of dust particles should be avoided. 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) or a non-disposable respirator to European Standard EN140 with a filter to EN143) should be worn when handling the veterinary medicinal product or medicated solution.

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 veterinary medicinal 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.

Do not smoke, eat or drink while handling the product.

Special precautions for the protection of the environment:

Not applicable.

3.6. Adverse events

Chicken (broiler), Pigs (for fattening), Turkey:

Undetermined frequency (cannot be estimated from the available data):	Allergic reaction[1] Photosensitivity[1] Disorders of gastrointestinal flora[2] (may result in digestive tract disorders)

[1] In this case, the withdrawal of the treatment should be recommended.
[2] If treatment is very prolonged.

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 and lactation or lay

Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, foetotoxic, maternotoxic effects.

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

The use is not recommended during pregnancy or lactation

3.8 Interaction with other medicinal products and other forms of interaction

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 as tetracyclines are bacteriostatic antimicrobials, do not administer in conjunction with bactericidal antibiotics like beta-lactames. It is advised that the interval between administration of other products containing polyvalent cations should be 1-2 hours because they limit the absorption of tetracycline.

Doxycycline increases the action of anticoagulants.

3.9 Administration routes and dosage

In drinking water use.

Chicken (broiler): 20 mg doxycycline / kg b.w. / day (corresponding to 40 mg of veterinary medicinal product / kg b.w. / day), for 3-5 days.

Turkey: 20 mg doxycycline / kg b.w. / day (corresponding to 40 mg of veterinary medicinal product / kg b.w. / day), for 5 days.

Pig (for fattening): 10 mg doxycycline / kg b.w. / day (corresponding to 20 mg of veterinary medicinal product / kg b.w. / day), for 5 days.

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:

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

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

The intake of medicated water depends on the clinical conditions of the animals. In order to obtain the correct dosage, the concentration of doxycycline may need to be adjusted accordingly.

Do not use at concentrations lower than 0.23 g of powder /l in drinking water with pH higher or equal to 7.5 to avoid precipitation.

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.
Only sufficient medicated drinking water should be prepared to cover daily requirements.

The use of suitably calibrated measuring 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. It is recommended to prepare a concentrated pre-solution - approximately 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.

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

The administration of 40 mg/kg b.w. in pigs and 80 mg/kg in chickens (in both species 4 times the recommended dose), for 5 days did not cause any adverse reaction.

In case of overdose treatment should be suspended and symptomatic treatment established.

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

3.12 Withdrawal periods

Pigs:
Meat and offal: 6 days

Chicken:
Meat and offal: 6 days
Eggs: Not for use in birds producing or intended to produce eggs for human consumption.

Turkey:
Meat and offal: 9 days
Eggs: 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 bacteriostatic antibiotic that acts by interfering with the bacterial protein synthesis of sensitive species.

Doxycycline is a semi-synthetic tetracycline derived from oxytetracycline. It acts on the subunit 30 S of the bacterial ribosome, to which is bound reversibly, blocking the union between aminoacyl-tRNA(transfer RNA) to the mRNA-ribosome complex, preventing the addition of new aminoacids into the growing peptide chain an thus interfering with protein synthesis.

Doxycycline is active against *Mycoplasma spp*. (chickens and turkeys), and *Pasteurella multocida* (fattening pigs).

Sensitivity of Doxycycline against *Pasteurella multocida* strains isolated from fattening pigs in 2004 has been determined, by means of agar dilution method. MIC_{90} values found are shown in next table (source of breakpoints: NCCLS 2000).
Concentration range used: 0.065 – 16 μg/ml.

NCCLS 2000	*Pasteurella multocida*
MIC_{90}	0.250
Breakpoints	Sensitive ≤ 4μg/ml

MIC_{90} of microorganisms involved in porcine respiratory complex

Sensitivity of Doxycycline against *Mycoplasma gallisepticum* strains isolated from turkeys between 2007 - 2010 has been determined, by means of agar dilution method. MIC_{90} values found are shown in next table.

Strains	**MIC_{90} Ug/ml**
M.gallisepticum	0.5

There are at least two mechanisms of resistance to tetracyclines:

One mechanism is evidenced by decreased ribosome affinity for the tetracycline-Mg^{2+} complex owing to chromosomal mutations. It is a ribosomal protection mechanism, in which protein synthesis is resistant to inhibition through a cytoplasmic protein (Prescott et al., 2000).
The most important mechanism of acquired resistance to tetracyclines is plasmid mediated, and is evidenced by a decrease in the cellular accumulation of the drug. The basis of this decrease is a reduction of the active transport of tetracyclines into the cell due to alterations of the external cellular membrane and increased efflux (or active pump elimination) by acquisition of new transport systems of cytoplasmic membrane. (Prescott et al., 2000). The alteration in the transport system is produced by inducible proteins codified in plasmids and transposons. Because the action mechanism of all tetracyclines has the same base, when resistance occurs, normally there is cross-resistance and complete within its group.

Resistance to tetracyclines may not only be the result of therapy with tetracyclines, but may also be caused by therapy with other antibiotics leading to selection of multi-resistant strains including tetracyclines. Although minimal inhibitory concentrations (MIC) tend to be lower for doxycycline than for older generation tetracyclines, pathogens resistant to one tetracycline are generally also resistant to doxycycline (cross resistance). Both long term treatment and treating for an insufficient length of time and/or sub-therapeutic dosages can select for antimicrobial resistance and should be avoided.

4.3 Pharmacokinetics

Doxycycline is bioavailable after oral administration. When orally administered, it reaches values greater than 70% in most species.

Feeding can modify the oral bioavailability of Doxycycline. In fasting conditions bioavailability is around 10 – 15% greater than when the animal is fed. Doxycycline is well distributed through the body as it is highly lipid soluble. It reaches well irrigated tissues as well as peripheral ones. It accumulates in liver, kidney, bones and intestine; enterohepatic recycling occurs. In lungs it always reaches higher concentrations than in plasma. Therapeutic concentrations have been detected in aqueous humour, myocardium, reproductive tissues, brain and mammary gland. Plasma protein binding is 90 – 92%.
40% of drug is metabolized and largely excreted through faeces (biliary and intestinal route), mainly as microbiologically inactive conjugates.

Chicken (broiler):
After oral administration, doxycycline is quickly absorbed; achieving maximum concentrations (C_{max}) around 1.5 h. Bioavailability is 75%. Absorption is decreased in the presence of aliment in gastrointestinal tract, bioavailability is then around 60% and the time to achieve the maximum concentration peak is significantly elongated, (T_{max}) 3.3 h.

Pigs (for fattening):
Treatment with the recommended dosage, maximum blood concentration in steady state ($C_{max\text{-}ss}$) was 0.83 μg/ml (SD = 0.29), minimum blood concentration in steady state ($C_{min–ss}$) was 0.22 and $C_{ave\text{-}ss}$= 0.49
After oral administration of 10 mg doxycycline /kg bw in pigs the bioavailability was 24.8 ± 4.6%. The elimination half-life ($t_{1/2}$) was 4.6 h; plasmatic clearance was 0.15 l/h.kg and apparent distribution volume was 0.89 l/kg.

Turkey:
Treatment with the recommended dosage, maximum blood concentration in steady state ($C_{max\text{-}ss}$) was 4.12 μg/ml (, minimum blood concentration in steady state ($C_{ave\text{-}ss}$) was 2.27 μg/ml and AUC_{ss}= 241.5 μg.h/ml.

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

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

5.2 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: use immediately.

Shelf life after dissolution according to directions: 24 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

Heat-sealed bag of 1 kg formed from polypropylene/aluminium/low density polyethylene laminate.

Pack sizes:
1 bag of 1 kg
Drums with 5 bags of 1 kg.
Cardboard box with 10 bags of 1 Kg
Drums with 25 bags of 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

LABORATORIOS CALIER, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorization:

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 III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Label for Cardboard drums containing 5 bags of 1 kg or 10 bags of 1 kg or 25 bags of 1 kg.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxycycline Calier 500 mg/g powder for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Doxycycline ..... 500 mg/g
(equivalent to 577 mg/g of doxycycline hyclate)

3. PACKAGE SIZE

5 x 1 kg
10 x 1 kg
25 x 1 kg

4. TARGET SPECIES

Chicken (broiler), Pigs (for fattening), Turkey

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Pigs:
Meat and offal: 6 days

Chicken:
Meat and offal: 6 days
Eggs: Not for use in birds producing or intended to produce eggs for human consumption.

Turkey:
Meat and offal: 9 days
Eggs: Not for use in birds producing or intended to produce eggs for human consumption.

8. EXPIRY DATE

Exp {mm/yyyy}

Once opened, use immediately.
Once diluted, use within 24 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

LABORATORIOS CALIER, S.A.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Fold-out (concertina) label for bags of 1 kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxycycline Calier 500 mg/g powder for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Doxycycline 500 mg/g
(equivalent to 577 mg/g of doxycycline hyclate)

3. TARGET SPECIES

Chicken (broiler), Pigs (for fattening), Turkey

4. ROUTES OF ADMINISTRATION

In drinking water use.

Read the package leaflet before use

5. WITHDRAWAL PERIODS

Withdrawal period:

Pigs:
Meat and offal: 6 days

Chicken:
Meat and offal: 6 days
Eggs: Not for use in birds producing or intended to produce eggs for human consumption.

Turkey:
Meat and offal: 9 days
Eggs: Not for use in birds producing or intended to produce eggs for human consumption.

6. EXPIRY DATE

Exp {mm/yyyy}

Once opened, use immediately.

Once diluted, use within 24 hours.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS CALIER, S.A.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Doxycycline Calier 500 mg/g powder for use in drinking water for chickens, turkeys and pigs

2. Composition

Each g contains:

Active substance:

Doxycycline ..... 500 mg
(equivalent to 577 mg of doxycycline hyclate)

Yellow powder.

3. Target species

Chicken (broiler), Pigs (for fattening), Turkey

4. Indications for use

Chicken (broiler) and turkey: Prevention and treatment of Chronic Respiratory Disease (CRD) caused by *Mycoplasma gallisepticum*.

Pigs (for fattening): Prevention and treatment of clinical respiratory infection caused by sensitive strains of *Pasteurella multocida*.

The presence of the disease in the herd must be established before the product is used.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with hepatic or renal disorders.

6. Special warnings

Special warnings:

Under-dosing and/or treating for an insufficient length of time are considered to promote the development of resistance in bacteria and should be avoided.
Sick animals may have a reduced appetite and an altered drinking pattern and should, if necessary, be medicated parenterally.

Special precautions for safe use in the target species:

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Avoid administration in oxidised drinking equipment.

Due to likely variability (time, geographical) in susceptibility of bacteria to doxycycline, bacteriological sampling and susceptibility testing are recommended.

Inappropriate use of the veterinary medicinal product 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 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.

Do not use at concentrations lower than 0.23 g of powder /l in drinking water with pH higher or equal to 7.5 to avoid precipitation.

Do not add acid to the medicated drinking water.

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

This veterinary medicinal product may cause contact dermatitis and/or hypersensitivity reactions if contact is made with skin or eyes (powder and solution) or if the powder is inhaled. People with known hypersensitivity to tetracyclines should handle the veterinary medicinal product or the medicated solution with caution.
Take measures to avoid producing dust when incorporating the veterinary medicinal product into water. Avoid direct contact with skin and eyes when handling the veterinary medicinal product to prevent sensitisation and contact dermatitis.

During preparation and administration of the medicated drinking water, skin contact with the product and inhalation of dust particles should be avoided. 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 or a non-disposable respirator to European Standard EN140 with a filter to EN143) should be worn when handling the veterinary medicinal product or medicated solution.

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 veterinary medicinal 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.

Do not smoke, eat or drink while handling the product.

Pregnancy and lactation:

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

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

The use is not recommended during pregnancy or lactation

Interaction with other medicinal products and other forms of interaction:

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 as tetracyclines are bacteriostatic antimicrobials, do not administer in conjunction with bactericidal antibiotics like beta-lactames. It is advised that the interval between administration of other products containing polyvalent cations should be 1-2 hours because they limit the absorption of tetracycline.

Doxycycline increases the action of anticoagulants.

Overdose:

The administration of 40 mg/kg b.w. in pigs and 80 mg/kg in chickens (in both species 4 times the recommended dose), for 5 days did not cause any adverse reaction.

In case of overdose treatment should be suspended and symptomatic treatment established.

Special restrictions for use and special conditions for use:

Major incompatibilities:

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

7. Adverse events

Chicken (broiler), Pigs (for fattening), Turkey:

Undetermined frequency (cannot be estimated form the available data):	Allergic reaction[1] Photosensitivity[1] Disorders of gastrointestinal flora[2] (may result in digestive tract disorder)

[1] In this case, the withdrawal of the treatment should be recommended.

[2] If treatment is very prolonged.

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

In drinking water use.

Chicken (broiler): 20 mg doxycycline (equivalent to 40 mg of veterinary medicinal product)/ kg b.w. / day, for 3-5 days.

Turkey: 20 mg doxycycline (equivalent to 40 mg of veterinary medicinal product)/ kg b.w. / day, for 5 days.

Pig (for fattening): 10 mg doxycycline (equivalent to 20 mg of veterinary medicinal product)/ kg b.w. / day, for 5 days.

9. Advice on correct administration

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

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

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

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.

Do not use at concentrations lower than 0.23 g of powder /l in drinking water with pH higher or equal to 7.5 to avoid precipitation.

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.

Only sufficient medicated drinking water should be prepared to cover daily requirements.

The use of suitably calibrated measuring 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. It is recommended to prepare a concentrated pre-solution - approximately 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.

10. Withdrawal periods

Pigs:
Meat and offal: 6 days

Chicken:
Meat and offal: 6 days
Eggs: Not for use in birds producing or intended to produce eggs for human consumption.

Turkey:
Meat and offal: 9 days
Eggs: 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 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 dissolution according to directions: 24 hours.
Shelf life after first opening the immediate packaging: use immediately.

12. Special precautions for the 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 systems. These measures should help to protect the environment.

Ask you 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

Pack sizes:

1 bag of 1 kg
Drums with 5 bags of 1 kg.
Cardboard box with 10 bags of 1 Kg
Drums with 25 bags of 1 kg.

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 manufacturer responsible for batch release and contact details to report suspected adverse reactions:

LABORATORIOS CALIER, S.A. [DE, ES, FR, IT, PL, CZ]
Calle Barcelonés 26
Polígono Industrial del Ramassà
08520 Les Franqueses del Vallès
Barcelona.
Spain

CALIER PORTUGAL, S.A. [PT]
Centro Empresarial Sintra-Estoril II
Rua Pé de Mouro, Edifício
C Estrada de Albarraque
2710 - 335 Sintra
Portugal

Manufacturer responsible for batch release [PT]:
LABORATORIOS CALIER, S.A.
Calle Barcelonés 26
Polígono Industrial del Ramassà
08520 Les Franqueses del Vallès
Barcelona.
Spain