[Version 9,07/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Belaflor 200 mg/ml solution for use in drinking water for chickens and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml solution contains:

Active substance:
200 mg florfenicol.

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Dimethylacetamid
Glycerol formal

Clear, slightly yellowish solution

3. CLINICAL INFORMATION

3.1 Target species

Chickens (broilers, pullets), pigs

3.2 Indications for use for each target species

Chickens:
For the treatment of infections caused by *E. coli*.

Pigs:
For the treatment of pleuropneumonia caused by *Actinobacillus pleuropneumoniae*, atrophic rhinitis caused by *Pasteurella multocida*, Glässer's disease caused by *Glaesserella parasuis*.

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 excipient.

3.4 Special warnings

The oral uptake of medication by animals may be altered as a consequence of illness. In case of insufficient water uptake, animals should be treated parenterally instead, using a suitable injectable product prescribed by the veterinarian.

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.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to florfenicol. In addition to medication, it is important to ensure proper husbandry conditions, including good hygiene, proper ventilation and avoiding crowded conditions.

Not for use for prophylaxis.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product may cause hypersensitivity reactions (allergy). People with known hypersensitivity to florfenicol or any of the excipients should avoid contact with the product.

This product may cause irritation to the skin and eyes. Avoid direct contact with the product. Wear gloves and protective glasses during the use of the product.

This product contains dimethylacetamide and glycerol formal, which has been shown to have the potential to affect the development of unborn children. Pregnant women and women of child-bearing age should avoid working with this product.

If accidental contact occurs, rinse the affected area with large amounts of clean water. If symptoms develop following cutaneous, ocular or oral exposure, seek medical advice and show this warning to the physician.

Do not eat, drink or smoke during use.

Wash hands with soap and water after use.

3.6 Adverse events

Chickens:
There are no known side effects in chicken.

Pigs:

Undetermined frequency (Frequency cannot be estimated from the available data):	Anal irritation[1] Soft faeces[1] Decreased drinking[2] Constipation[3] Unusual stool colour[3]

[1] Reddening around the anus and soft faeces may often occur after administration of this medicine. These abnormalities are of a temporary nature, have a short duration and do not affect the general condition of the animals.

[2] A slight reduction in water consumption may be observed during treatment.

[3] Dark brown faeces and constipation may be observed during treatment.

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 section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The product contains dimethylacetamide, which is considered to be a reproductive toxicant. The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay. The use is hence not recommended during pregnancy, lactation and lay.

Do not use in breeding animals.

3.8 Interactions with other medicinal products and other forms of interaction

Do not use concomitantly with bactericidal antibiotics.

3.9 Administration routes and dosage

For use in drinking water.

Chickens:
The recommended dosage is 20 mg florfenicol per kg bodyweight per day (corresponding to 0.1 ml product/kg bw/day). The treatment duration is 5 days.

Pigs:
The recommended dosage is 10 mg florfenicol per kg bodyweight per day (corresponding to 0.05 ml product/kg bw/day) i.e. the daily dose for a pig weighing 100 kg is 5 ml of the product.
The treatment duration is 5 days.

In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated. 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 florfenicol may need to be adjusted accordingly. The daily water consumption and the dose per kilogram of body weight should be used to calculate the required concentration in the medicated water, according to the formula below:

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

All animals to be treated should have sufficient access to the water supply system to ensure adequate consumption of the medicated drinking water.

For use in drinking water, a stock solution should be prepared first. Prepare the solution with fresh potable water. Complete dissolution of the product should be ensured by gently mixing the product until fully dissolved. The homogeneity of the medicated drinking water should be kept during the administration to animals. Any medicated water which is not consumed within 24 hours should be discarded and the medicated drinking water replenished. After completion of the medication treatment, the watering system should be properly cleaned to avoid the intake of sub-therapeutic amounts of the active substance.

Solubility in water varies depending on temperature and water quality. Under worst case conditions (4 °C and hard water) a maximum solubility of approximately 0.8 g/L has been confirmed. In soft water and 25°C 1.0 g/L can be dissolved.

For stock solutions and when using a proportioner, take care not to exceed the maximum solubility which can be achieved under the given conditions. Adjust flow rate settings of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated.

If there is no significant improvement after 3 treatment days, the diagnosis should be reviewed and if necessary, the treatment should be changed.

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

In case of an overdose, weight loss and decreased water consumption, perianal erythema and dropsy, and changes in certain haematological and biochemical parameters indicative of dehydration may be observed.

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

Chickens
Meat and offal: 8 days.
Not for use in birds producing or intended to produce eggs for human consumption.

Pigs
Meat and offal: 23 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01BA90

4.2 Pharmacodynamics

Florfenicol is a synthetic, broad-spectrum antibiotic with a bacteriostatic effect. When bound to the 70 S subunit of ribosomes in the protoplasm, it blocks the action of the peptidyl transferase enzyme. As a consequence, protein synthesis is inhibited on ribosomes of florfenicol-sensitive bacteria.
A thiamphenicol derivative substituted with a fluorine atom on the hydroxyl group of florfenicol. This renders it effective against chloramphenicol-resistant, acetyltransferase-producing bacteria.
Laboratory tests have demonstrated the activity of florfenicol against a number of pathogenic bacteria isolated in poultry diseases, including *Escherichia coli* and *Actinobacillus pleuropneumoniae, Pasteurella multocida, Glaesserella parasui*s isolated in pig diseases.
One main resistance gene (*floR*) has been identified leading to resistance to florfenicol. Additional genes have also been identified, but play a minor role in resistance mechanism. The resistance genes are most often located on mobile genetic elements, such as plasmids or transposons.

For isolates collected from pigs with respiratory diseases the following CLSI breakpoints have been established for *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*: susceptible ≤ 2 μg/ml, intermediate 4 μg/ml and resistant ≥ 8 μg/ml.
No CLSI breakpoint has been established for *Glaesserella parasui*s.
For isolates collected from chicken with *E. coli* infections, no CLSI breakpoint has been established for *E. coli*.

4.3 Pharmacokinetics

Florfenicol is distributed well throughout the tissues. It reaches maximum concentration in the kidneys, the liver, the bladder, the lungs and the intestinal tract.
Approximately 50% of florfenicol is excreted from the body in an unchanged form, with the remainder being excreted as metabolites (mostly florfenicol amine).

Environmental properties
Manure from treated animals may be harmful to cyanobacteria and terrestrial plants.

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.

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: 28 days
Shelf life after dilution according to directions: 24 hours

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

1000 ml polyethylene bottle with a screw cap or 5000 ml in a polyethylene canister with a screw cap

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.
The veterinary medicinal product should not enter water courses as florfenicol may be dangerous for aquatic organisms.
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

Bela-Pharm GmbH & Co.KG

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.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER/ IMMEDIATE PACKAGE
The applicant does not intend to have a separate template and reduced texts for the immediate label.
{Container}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Belaflor 200 mg/ml solution for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml solution contains:

Active substance:
Florfenicol 200 mg

3. PACKAGE SIZE

1000 ml
5000 ml

4. TARGET SPECIES

Chickens (broilers, pullets), pigs

5. INDICATIONS

Not applicable in case of products subject to veterinary prescription.

6. ROUTES OF ADMINISTRATION

Solution for use in drinking water

7. WITHDRAWAL PERIODS

Withdrawal period:

Chickens
Meat and offal: 8 days.
Not for use in birds producing or intended to produce eggs for human consumption.

Pigs
Meat and offal: 23 days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within…

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

bela-pharm GmbH & Co.KG

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Belaflor 200 mg/ml solution for use in drinking water for chickens and pigs

2. Composition

Each ml solution contains:

Active substance:
Florfenicol 200 mg

Clear, slightly yellowish solution.

3. Target species

Chickens (broilers, pullets), pigs

4. Indications for use

Chickens:
For the treatment of infections caused by *E. coli*.

Pigs:
For the treatment of pleuropneumonia caused by *Actinobacillus pleuropneumoniae*, atrophic rhinitis caused by *Pasteurella multocida*, Glässer's disease caused by *Glaesserella parasuis*.

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 excipient.

6. Special warnings

Special warnings:
The oral uptake of medication by animals may be altered as a consequence of illness. In case of insufficient water uptake, animals should be treated parenterally instead, using a suitable injectable product prescribed by the veterinarian.

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.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to florfenicol. In addition to medication, it is important to ensure proper husbandry conditions, including good hygiene, proper ventilation and avoiding crowded conditions.

Not for use for prophylaxis.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product may cause hypersensitivity reactions (allergy). People with known hypersensitivity to florfenicol or any of the excipients should avoid contact with the product.

This product may cause irritation to the skin and eyes. Avoid direct contact with the product. Wear gloves and protective glasses during the use of the product.

This product contains dimethylacetamide and glycerol formal, which has been shown to have the potential to affect the development of unborn children. Pregnant women and women of child-bearing age should avoid working with this product.

If accidental contact occurs, rinse the affected area with large amounts of clean water. If symptoms develop following cutaneous, ocular or oral exposure, seek medical advice and show this warning to the physician.

Do not eat, drink or smoke during use.

Wash hands with soap and water after use.

Pregnancy, lactation and lay:
The product contains dimethylacetamide, which is considered to be a reproductive toxicant.
The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay. The use is hence not recommended during pregnancy and lactation.

Do not use in breeding animals.

Interaction with other medicinal products and other forms of interaction:
Do not use concomitantly with bactericidal antibiotics.

Overdose:
In case of an overdose, weight loss and decreased water consumption, perianal erythema and dropsy, and changes in certain haematological and biochemical parameters indicative of dehydration may be observed.

Special restrictions for use and special conditions for use:
Not applicable.

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

7. Adverse events

Chickens:
There are no known side effects in chicken.

Pigs:

Undetermined frequency (Frequency cannot be estimated from the available data):	Anal irritation[1] Soft faeces[1] Decreased drinking[2] Constipation[3] Unusual stool colour[3]

[1] Reddening around the anus and soft faeces may often occur after administration of this medicine. These abnormalities are of a temporary nature, have a short duration and do not affect the general condition of the animals.

[2] A slight reduction in water consumption may be observed during treatment.

[3] Dark brown faeces and constipation may be observed during treatment.

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><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

For use in drinking water.

Chickens:
The recommended dosage is 20 mg florfenicol per kg bodyweight per day (corresponding to 0.1 ml product/kg bw/day). The treatment duration is 5 days.

Pigs:
The recommended dosage is 10 mg florfenicol per kg bodyweight per day (corresponding to 0.05 ml product/kg bw/day), i.e. the daily dose for a pig weighing 100 kg is 5 ml of the product.
The treatment duration is 5 days.

In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated. 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 florfenicol may need to be adjusted accordingly.

The daily water consumption and the dose per kilogram of body weight should be used to calculate the required concentration in the medicated water, according to the formula below:

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

If there is no significant improvement after 3 treatment days, the diagnosis should be reviewed and if necessary, the treatment should be changed.

9. Advise on correct administration

All animals to be treated should have sufficient access to the water supply system to ensure adequate consumption of the medicated drinking water.

For use in drinking water, a stock solution should be prepared first. Prepare the solution with fresh potable water. Complete dissolution of the product should be ensured by gently mixing the product until fully dissolved. The homogeneity of the medicated drinking water should be kept during the administration to animals. Any medicated water which is not consumed within 24 hours should be discarded and the medicated drinking water replenished. After completion of the medication treatment, the watering system should be properly cleaned to avoid the intake of sub-therapeutic amounts of the active substance.

Solubility in water varies depending on temperature and water quality. Under worst case conditions (4 °C and hard water) a maximum solubility of approximately 0.8 g/L has been confirmed. In soft water and 25°C 1.0 g/L can be dissolved.

For stock solutions and when using a proportioner, take care not to exceed the maximum solubility which can be achieved under the given conditions. Adjust flow rate settings of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated.

10. Withdrawal periods

Chickens
Meat and offal: 8 days.
Not for use in birds producing or intended to produce eggs for human consumption.

Pigs
Meat and offal: 23 days

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage condition.

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

Shelf life after first opening the immediate packaging: 28 daysShelf life after dilution according to directions: 24 hours….

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
This veterinary medicinal product should not enter water courses as florfenicol may be dangerous for aquatic organisms.
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

1000 ml container
5000 ml container

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. Contact details

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

bela-pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta
Germany

Local representatives and contact details to report suspected adverse reactions:

[To be completed nationally]

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

17. Other information

Manure from treated animals may be harmful to cyanobacteria and terrestrial plants.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

{Combined Label on Container}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Belaflor 200 mg/ml solution for use in drinking water for chickens and pigs

2. COMPOSITION

Each ml solution contains:

Active substance:
Florfenicol 200 mg

3. PACKAGE SIZE

1000 ml
5000 ml

4. TARGET SPECIES

Chickens (broilers, pullets), pigs

5. INDICATIONS FOR USE

Indications for use

Chickens:
For the treatment of infections caused by *E. coli*.

For the treatment of pleuropneumonia caused by *Actinobacillus pleuropneumoniae*, atrophic rhinitis caused by *Pasteurella multocida*, Glässer's disease caused by *Glaesserella parasuis* sensitive to florfenicol.

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

6. CONTRAINDICATIONS

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

7. SPECIAL WARNINGS

Special warnings
The oral uptake of medication by animals may be altered as a consequence of illness. In case of insufficient water uptake, animals should be treated parenterally instead using a suitable injectable product prescribed by the veterinarian.

Special warnings 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.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to florfenicol. In addition to medication, it is important to ensure proper husbandry conditions, including good hygiene, proper ventilation and avoiding crowded conditions.

Not for use for prophylaxis.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product may cause hypersensitivity reactions (allergy). People with known hypersensitivity to florfenicol or any of the excipients should avoid contact with the product.

This product may cause irritation to the skin and eyes. Avoid direct contact with the product. Wear gloves and protective glasses during the use of the product.

This product contains dimethylacetamide and glycerol formal, which has been shown to have the potential to affect the development of unborn children. Pregnant women and women of child-bearing age should avoid working with this product.

If accidental contact occurs, rinse the affected area with large amounts of clean water. If symptoms develop following cutaneous, ocular or oral exposure, seek medical advice and show this warning to the physician.

Do not eat, drink or smoke during use.

Wash hands with soap and water after use.

Pregnancy, lactation and lay:
The product contains dimethylacetamide, which is considered to be a reproductive toxicant. The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay. The use is hence not recommended during pregnancy and lactation.

Do not use in breeding animals.

Interaction with other medicinal products and other forms of interaction:
Do not use concomitantly with bactericidal antibiotics.

Overdose (symptoms, emergency procedures, antidotes):
In case of an overdose, weight loss and decreased water consumption, perianal erythema and dropsy, and changes in certain haematological and biochemical parameters indicative of dehydration may be observed.

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

8. ADVERSE EVENTS

Adverse reactions

Chickens:
There are no known side effects in chicken.

Pigs:

Undetermined frequency (Frequency cannot be estimated from the available data):	Anal irritation[1] Soft faeces[1] Decreased drinking[2] Constipation[3] Unusual stool colour[3]

[1] Reddening around the anus and soft faeces may often occur after administration of this medicine. These abnormalities are of a temporary nature, have a short duration and do not affect the general condition of the animals.

[2] A slight reduction in water consumption may be observed during treatment.

[3] Dark brown faeces and constipation may be observed during treatment.

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><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}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, route(s) and method of administration

For use in drinking water.

Chickens:
The recommended dosage is 20 mg florfenicol per kg bodyweight per day (corresponding to 0.1 ml product/kg bw/day). The treatment duration is 5 days.

Pigs:
The recommended dosage is 10 mg florfenicol per kg bodyweight per day (corresponding to 0.05 ml product/kg bw/day) i.e. the daily dose for a pig weighing 100 kg is 5 ml of the product.
The treatment duration is 5 days.

In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated. 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 florfenicol may need to be adjusted accordingly. The daily water consumption and the dose per kilogram of body weight should be used to calculate the required concentration in the medicated water, according to the formula below:

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

If there is no significant improvement after 3 treatment days, the diagnosis should be reviewed and if necessary, the treatment should be changed.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

All animals to be treated should have sufficient access to the water supply system to ensure adequate consumption of the medicated drinking water.

For use in drinking water, a stock solution should be prepared first. Prepare the solution with fresh potable water. Complete dissolution of the product should be ensured by gently mixing the product until fully dissolved. The homogeneity of the medicated drinking water should be kept during the administration to animals. Any medicated water which is not consumed within 24 hours should be discarded and the medicated drinking water replenished. After completion of the medication treatment, the watering system should be properly cleaned to avoid the intake of sub-therapeutic amounts of the active substance.

Solubility in water varies depending on temperature and water quality. Under worst case conditions (4 °C and hard water) a maximum solubility of approximately 0.8 g/L has been confirmed. In soft water and 25°C 1.0 g/L can be dissolved.

For stock solutions and when using a proportioner, take care not to exceed the maximum solubility which can be achieved under the given conditions. Adjust flow rate settings of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated.

11. WITHDRAWAL PERIODS

Withdrawal periods:

Chickens
Meat and offal: 8 days.
Not for use in birds producing or intended to produce eggs for human consumption.

Pigs
Meat and offal: 23 days

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage condition.

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

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater.
This veterinary medicinal product should not enter water courses as florfenicol may be dangerous for aquatic organisms.
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.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

EU/0/00/000/000

Pack sizes
1000 ml container
5000 ml container

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
bela-pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta
Germany

Local representatives and contact details to report suspected adverse reactions:

[To be completed nationally]

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

18. OTHER INFORMATION

Other information
Manure from treated animals may be harmful to cyanobacteria and terrestrial plants.

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. Expiry date

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days
Shelf life after dilution according to directions: 24 hours

21 BATCH NUMBER

<Batch> <Lot> <BN> {number}