ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BAG 0.5 kg
BAG 1 kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amphen 200 mg/g granules for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Florfenicol 200 mg/g

3. PACKAGE SIZE

0.5 kg
1 kg

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: 20 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf-life after first opening the bag: 3 months.
Once opened use by:….

9. SPECIAL STORAGE PRECAUTIONS

Store in the original container in order to protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

14. MARKETING AUTHORISATION NUMBERS

Vm 30282/4043

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Amphen 200 mg/ml granules for use in drinking water for pigs.

2. Composition

Each gram contains:

Active substance:
Florfenicol 200 mg

Excipients:
Butylhydroxytoluene (E321) 1 mg
Disodium edetate 1 mg

White to cream waxy granules.

3. Target species

Pigs.

4. Indications for use

Treatment and metaphylaxis of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol. The presence of the disease must be established in the group before metaphylactic treatment.

5. Contraindications

Do not administer to boars intended for breeding purposes.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients
Do not use in case of known resistance to florfenicol.

6. Special warnings

Special warnings:
In case of insufficient water intake, animals should be treated parenterally. During treatment, unmedicated drinking water should only be administered after the daily amount of medicated drinking water has been ingested by pigs. The veterinary medicinal product is not intended to be used together with other antibiotics.

Special precautions for safe use in the target species:
Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to florfenicol and may decrease the effectiveness of treatment with amphenicols due to the potential for cross-resistance. Treatment should not exceed 5 days. During treatment, increased serum calcium may also be observed.
Do not use the veterinary medicinal product with chlorinated water.

Studies in laboratory animals have not revealed any evidence of potential embryotoxic or foetotoxic effect of florfenicol. The safety of the veterinary medicinal product in sows has not been established during pregnancy and lactation. The use is not recommended during pregnancy and lactation.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
In case of overdosing, a decrease in weight gain, food and water consumption, peri-anal erythema and oedema and modification of some haematological and biochemical parameters indicative of dehydration may be observed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to florfenicol, polysorbate 80 or polyethylene glycol should avoid contact with the veterinary medicinal product. Personal protective equipment consisting of protective gloves, safety glasses and clothing should be worn when handling the veterinary medicinal product. If you develop symptoms following exposure such as skin rash, seek medical advice immediately and show the package leaflet or the label to the physician.

This veterinary medicinal product may be slightly irritating to the eyes and/or skin. Avoid contact with the skin and eyes, including hand-to-eye-contact. Wear safety glasses. In case of accidental spillage onto eyes, wash them immediately with water. In case of contact with the skin, wash immediately the affected area and take the contaminated clothes off.

This veterinary medicinal product may be harmful after ingestion. Do not smoke, eat or drink when handling the veterinary medicinal product or mixing the medicated drinking water.

Special precautions for the protection of the environment:
Manure from treated animals may be harmful to terrestrial plants.

Pregnancy and lactation:
Studies in laboratory animals have not produced any evidence of potential embryotoxic or foetotoxic effect of florfenicol.
The safety of the veterinary medicinal product in sows has not been established during pregnancy and lactation. The use is not recommended during pregnancy and lactation.

Overdose:
In case of overdosing, a decrease in weight gain, food and water consumption, peri-anal erythema and oedema and modification of some 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.

7. Adverse events

Very common (>1 animal / 10 animals treated):
Diarrhoea[1] Erythema[1,2], Oedema[1,2].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Rectal prolapse[3].
Undetermined frequency (cannot be estimated from the available data):
Decreased drinking[4], Inappetence Unusual stool colour[5], Constipation.

[1] transient, [2] peri-anal or rectal, [3] resolves without treatment, [4] slight, [5] dark brown

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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

10 mg florfenicol /kg bodyweight per day in drinking water for 5 consecutive days.
In drinking water use.

9. Advice on correct administration

The daily amount of veterinary medicinal product to be mixed with drinking water can be calculated based on the Total Body Weight (TBW) of the group to be treated with the following formula:

$$\text{Amount of veterinary medicinal product (in grams) per day*} = \frac{\text{Total Body Weight of the group (TBW) in kg}}{20}$$

** to be mixed with the estimated total water consumption of the group in 24 hours.*

The examples of medicated drinking water in the table below are calculated by applying the formula and by assuming that pigs drink 8% or 10% of their bodyweight.

	TBW of the group (kg)	Veterinary medicinal product (g)	Estimated daily water consumption (L)	Veterinary medicinal product grams per 10 litres of water
Pigs drinking 8% of their bodyweight	500 kg	25 g	40 L	6.25 g/10 L
	1000 kg	50 g	80 L	
	5000 kg	250 g	400 L	
Pigs drinking 10% of their bodyweight	500 kg	25 g	50 L	5 g/10 L
	1000 kg	50 g	100 L	
	5000 Kg	250 g	500 L	

The maximum solubility of the veterinary medicinal product granules is 2.5 g/litre in water at 10 °C and 20 °C and 2.0 g/L at 5 °C. Dissolution may take up to 30 minutes. During dissolution the solution should be stirred for at least 5 minutes at 50 RPM. Solutions should be checked visually for complete dissolution.

FOR BULK TANK:
Any solution for use in a header tank must be limited to not more than the maximum solubility.

FOR PROPORTIONER:
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.

To treat 5,000 kg of pigs, drinking 10% of their bodyweight, at the dose rate of 10 mg/kg:
1. Fill the proportioner with 100 L drinking water (temperature not below 10 °C).
2. Add 250g of veterinary medicinal product to the proportioner.
3. Mix thoroughly until visually dissolved.
4. Set the proportioner to 20%.
5. Turn on the proportioner.

In order to ensure correct dosing and to prevent underdosing, the body weight of the group should be calculated as precisely as possible and water consumption should be monitored. The required quantity of granules should be measured by suitably calibrated weighing equipment.

The uptake of water depends on several factors including the age, the clinical state of the animals and the local conditions such as ambient temperature and humidity. The daily water consumption can be underestimated (e.g. reduced to 6% of bodyweight) in order to ensure total consumption of medicated water during the day (fresh drinking water can be made available following the consumption of the medicated water). If it is not possible to obtain sufficient uptake of medicated water animals should be treated parenterally.

Use of the veterinary medicinal product should be based on susceptibility testing and take into account official and local antimicrobial policies.

Medicated drinking water should be replaced every 24 hours.

10. Withdrawal periods

Meat and offal: 20 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original container in order to protect from light.

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 first opening the immediate packaging: 3 months. The bag is opened and closed by unzipping respectively zipping.
Shelf life after reconstitution according to directions: 24 hours.

12. Special precautions for disposal

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

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

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 30282/4043

The veterinary medicinal product is available in 0.5 kg and 1 kg resealable block bottom zipped bags made of polyethylene /aluminium/polyethylene terephthalate laminate.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium
<+32 3 292 83 05 or +32 3 288 18 49>
<pharmacovigilance@huvepharma.com>

Manufacturer responsible for batch release:
Laboratoria Smeets NV
Fotografielaan 42
2610 Wilrijk
Belgium

Local representatives <and contact details to report suspected adverse reactions>:

17. Other information

Gavin Hall

Approved 19 December 2024