PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS

BAG 0.5 kg
BAG 1 kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AMPHEN, 200 mg/g granules for use in drinking water for pigs

Florfenicol

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:
Active substance:
Florfenicol 200 mg

Excipients:
Butylhydroxytoluene (E321)
Disodium Edetate

3. PHARMACEUTICAL FORM

Granules for use in drinking water

4. PACKAGE SIZE

0.5 kg
1 kg

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use

8. WITHDRAWAL PERIOD

Withdrawal period: Meat and offal: 20 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}: DD/MM/YY
Shelf-life after first opening the bag: 3 months.
Once opened, use by:_____

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 30282/4043

17. MANUFACTURER'S BATCH NUMBER

Lot {number}:

B. PACKAGE LEAFLET

PACKAGE INSERT

AMPHEN, 200 mg/g granules for use in drinking water for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

AMPHEN, 200 mg/g granules for use in drinking water for pigs

Florfenicol

3. STATEMENT OF THE ACTIVE AND OTHER INGREDIENT (S)

Each g contains:

Active substance:

Florfenicol	200 mg

Excipients:

Butylhydroxytoluene (E321).	1 mg
Disodium Edetate	1 mg

White to cream waxy granules.

4. INDICATION(S)

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 known cases of hypersensitivity to the active substance or to any of the excipients
Do not use in case of known resistance to florfenicol

6. ADVERSE REACTIONS

A slight reduction of water consumption by the animals, inappetance, dark brown faeces and constipation may be observed during treatment.
Diarrhoea and/or peri-anal and rectal erythema/oedema have been observed very commonly in treated animals. These effects are transient.
Prolapse of the rectum, that resolves without treatment, has been observed very rarely in affected animals.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 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:

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

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

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)	Product (g)	Estimated daily water consumption (L)	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 product granules is 2.5 g/litre in water at 10°C and 20°C and 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 100L drinking water (temperature not below 10°C).
2. Add 250g of 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 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 PERIOD

Meat and offal: 20 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in the original package in order to protect from light.
Shelf-life after first opening the container: 3 months. The bag is opened and closed by unzipping respectively zipping.
Shelf life after reconstitution according to directions: 24 hours.
Do not use after the expiry date stated on the label after EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species:

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 product is not intended to be used together with other antibiotics.

Special precautions for use in animals:

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. It 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 product is used.
Use of the 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 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 product may cause hypersensitivity reactions. If you have known hypersensitivity to florfenicol, polysorbate 80 or polyethylene glycol, avoid skin contact with this product. Wear protective gloves and clothing when handling and mixing this 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 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 product may be harmful after ingestion. Do not smoke, eat or drink when handling the product or mixing the medicated drinking water.

Special precautions for the environment

Manure from treated animals may be harmful to terrestrial plants.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2021

15. OTHER INFORMATION

The 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.

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

Approved 29 December 2021