PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS

BAG 0.5 kg
BAG 1 kg
BAG 5 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 AND OTHER SUBSTANCES

1g 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 kg

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use in drinking water. Read the folding label before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Meat and offal: 20 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the folding label before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

Store in the original package.

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

Read the folding label 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 30282/4025

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)

1 g of granules contains:

Active substance:
Florfenicol 200 mg

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

White to cream waxy granules.

4. INDICATION(S)

For the treatment of swine respiratory disease associated with *Pasteurella multocida* susceptible to florfenicol.

5. CONTRAINDICATIONS

Do not administer to boars intended for breeding purposes.

Do not use in piglets less than 6 weeks old.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Diarrhoea has been very commonly reported (up to 30% of animals) and inflammation of the perianal area (up to 5 % of animals) has been commonly reported in treated animals. These effects are transient and normally resolve within 5 days. Rectal prolapse has been uncommonly reported.
A slight reduction in food consumption may be observed during treatment.

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, METHOD AND ROUTE(S) OF ADMINISTRATION

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

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 herd to be treated with the following formula:

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

* to be mixed with the estimated total water consumption of the herd 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 herd (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	

In order to ensure correct dosing and to prevent underdosing, the body weight of the herd 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. The maximum solubility of the product granules is 5 g/L. Medicated drinking water should be replaced every 24 hours.

FOR BULK TANK: To treat pigs drinking 10% of their bodyweight, at the dose of 10 mg/kg: add 5g product per 10L drinking water in the bulk tank and mix thoroughly until visually dissolved.
For pigs drinking 8% of their body weight, at a dose of 10mg/kg: add 6,25g product to every 10L drinking water in the tank and mix thoroughly until visually dissolved.

FOR PROPORTIONER: Convenient proportioner settings for the use of florfenicol in the drinking water is 20%

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.

The maximum solubility of the product granules is 5 g/litre in water at 20°C and and 2.0 g/L at 5°C. Any solutions for use in header tank must be limited to no more than 2.5 g/L.; Dissolution may take up to 30 minutes and solutions should be checked visually for complete dissolution. In order to ensure rapid dissolution, solutions should be prepared in accordance with the examples above. Otherwise, solutions should be visually inspected to ensure that dissolution is complete before the product is administered.

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

10. WITHDRAWAL PERIOD

Meat and offal: 20 days.

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 container: 3 months.
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:

If there is no significant improvement after 3 days of treatment, the diagnosis should be reviewed and if necessary the treatment should be changed.
In case of insufficient water intake, animals should be treated parenterally

Special precautions for use in the animal:

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.
The safety of the product during pregnancy and lactation has not been demonstrated.
Use of the product during pregnancy and lactation is therefore not recommended.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
After administration at 3 times the recommended dose a reduction in food and water consumption, together with a decrease in bodyweight has been observed. After administration at 3 times or more of the recommended dose, depression of some animals have been observed.

User warnings:

People with known hypersensitivity to florfenicol or any of the excipients should avoid contact with the veterinary medicinal product.
Contact of the product or the medicated drinking water with skin and eyes should be avoided.
Personal protective equipment consisting of homologated protective gloves, coverall and safety glasses should be worn when handling and mixing the veterinary medicinal product.
In case of accidental spillage onto eyes, wash them immediately with water. In case of contact with skin, wash immediately the affected area and take the contaminated clothes off.
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.
Do not smoke, eat or drink when handling the product or mixing the medicated drinking water.

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

15. OTHER INFORMATION

The product is available in 0.5 kg, 1 kg or 5 kg bags. 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 02 July 2018