ATLAS VETERINAIRE

ATLAFLOR

INJECTABLE SOLUTION

COMPOSITION

Florfenicol…….. 30g

Excipient qs…….. 100ml

PHARMACEUTICAL PROPERTIES

Florfenicol is a synthetic, broad-spectrum **antibiotic** active against most Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol is a **bacteriostatic** antibiotic, which acts by inhibiting bacterial protein synthesis at the ribosome level.

In vitro tests have shown that **florfenicol** is active against pathogenic bacteria most commonly implicated in respiratory disease including: *Mannheimia haemolytica* and *Pasteurella multocida* in cattle and sheep, and *Histophilus somni* in cattle.

Intramuscular administration of **florfenicol** at the recommended dose of 20 mg florfenicol per kg in cattle maintains effective blood levels for 48 hours. The mean maximum serum concentration (Cmax) of 3.37 µg/ml appears 3.3 hours (tmax) after administration. The mean serum concentration, 24 hours after administration, is 0.77 µg/ml.

Intramuscular administration of **florfenicol** at the recommended dose of 40 mg florfenicol per kg in cattle maintains effective plasma concentrations for 63 hours. The maximum serum concentration (Cmax) of approximately 5 µg/ml appears approximately 5.3 hours (tmax) after administration. The mean serum concentration 24 hours after administration is approximately 2 µg/ml. The mean elimination half-life is 18.3 hours.

After intramuscular administration of florfenicol (20 mg/kg) in sheep, the mean maximum serum concentration of 10 µg/ml is reached within 1 hour. After a third intramuscular administration, the maximum serum concentration of 11.3 µg/mL is reached in 1.5 hours. The elimination half-life is estimated at 13.76 ± 6.42 h. The bioavailability is about 90%.

TARGET SPECIES

Cattle and sheep.

INDICATIONS

Diseases with germs sensitive to florfenicol.

In cattle:

Treatment of respiratory tract infections due to *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni.* The presence of the disease in the herd should be established before treatment.

In sheep:

Treatment of respiratory tract infections due to *Mannheimia haemolytica* and *Pasteurella multocida.*

ADMINISTRATION AND DOSAGE

In cattle:

- **Deep intramuscular route:** 20 mg of florfenicol per kg of bodyweight, i.e. 1 ml of solution per 15 kg of bodyweight, twice at 48-hour intervals.
- **Subcutaneous route :** 40 mg of florfenicol per kg of body weight, i.e. 2 ml of solution for 15 kg of body weight quick, just once.
- The volume administered must not exceed 10 ml per site The injection must be carried injection. out in the neck of the animal.

In sheep:

- **Deep intramuscular route :** 20 mg of florfenicol per kg of body weight, i.e. 1 ml of solution for 15 kg bodyweight, per day for 3 consecutive days.
- The volume administered must not exceed 4 ml.

CONTRAINDICATIONS AND INTERACTIONS

- Do not administer to adult bulls and rams intended for breeding.
- Do not use in case of known hypersensitivity to the active substance.
- Do not use in animals producing milk for human consumption.
- Studies in laboratory animals have not shown any teratogenic or foetotoxic effects. However, the effects of florfenicol in cows and ewes on reproductive performance and pregnancy have not been evaluated. The use of the specialty should only be done after evaluation of the benefit/risk ratio by the veterinarian.

SIDE EFFECTS

In cattle:

- A decrease in food consumption as well as softening of faeces may occur during treatment. Treated animals regain their appetite quickly and completely as soon as treatment is stopped.

- The administration of the specialty by intramuscular and subcutaneous routes can cause lesions injection site inflammation that may persist for 14 days.
- In very rare cases, anaphylactic shock has been reported in cattle.

In sheep:

- A decrease in food consumption may occur during treatment. The treated animals regain their appetite quickly and completely as soon as the treatment is stopped.
- Administration of the product by intramuscular route may cause inflammatory lesions at the injection site which may persist for up to 28 days. As a rule, these lesions are mild and transient.

PRECAUTIONS FOR USE

Precautions for use in animals:

- The specialty should only be used after checking the sensitivity of the strains and should take into account the recommendations for antibiotic therapy.
- Respect the recommended dosage.

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

- In case of accidental contact with skin or eyes, rinse immediately with plenty of water.
- In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician or labeling.

WITHDRAWAL PERIOD

Meat and offal:

- Cattle : ÿ

30 days (intramuscular route)

ÿ 44 days (subcutaneous route)

- Sheep : 39 days

Milk: Do not use in animals producing milk for human consumption.

STORAGE CONDITIONS

- **Unopened container:** Keep the product in the commercial packaging, protected from light and at a temperature not exceeding 25°C.
- **After opening the bottle:** 4 weeks.

PHARMACEUTICAL FORM AND PRESENTATION

Solution for injection.

Bottles of 20, 50, 100 and 250 ml.