Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenflor 300 mg/ml solution for injection for cattle.
Florfenicol.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Florfenicol	300 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A light yellow to yellow, clear, viscous liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Diseases caused by florfenicol susceptible bacteria.
Preventive and therapeutic treatment of respiratory tract infections in cattle due to *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni*.
The presence of the disease in the herd should be established before preventive treatment.

4.3 Contraindications

Do not use in adult bulls intended for breeding purposes.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
See also section 4.7.
Do not use in case of resistance to the active substance.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Swab septum before removing each dose. Use a dry, sterile syringe and needle.
The product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Care should be taken to avoid accidental self-injection.
In case of accidental self injection, seek medical advice and show the label to the doctor.
Do not use the product in known cases of sensitivity to propylene glycol.

4.6 Adverse reactions (frequency and seriousness)

A decrease in food consumption and transient softening of the faeces may occur during the treatment period. The treated animals recover quickly and completely upon termination of treatment.
Administration of the product by the intramuscular route may cause swelling at the injection site which may persist for 14 days.
Inflammation at the injection site may persist up to 32 days after administration.
Administration of the product by the subcutaneous route may cause swelling and inflammation at the injection site which may persist at least for 41 days.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals have not revealed any evidence of embryo- or foetotoxic potential for florfenicol.
However, the effect of florfenicol on bovine reproductive performance and pregnancy has not been assessed.
Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For treatment:
IM route: 20 mg/kg bodyweight (1 ml/15 kg) to be administered twice 48 hours apart using a 16 gauge needle.
SC route: 40 mg/kg bodyweight (2 ml/15 kg) to be administered once only using a 16 gauge needle.

For prevention:
SC route: 40 mg/kg bodyweight (2 ml/15kg) to be administered once only using a 16 gauge needle.
The dose volume given at any one injection site should not exceed 10 ml.
The injection should only be given in the neck.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid under dosing.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None.

4.11 Withdrawal Period(s)

Meat and offal: by IM (at 20 mg/kg bodyweight, twice): 30 days
by SC (at 40 mg/kg bodyweight, once): 44 days

Milk: Not permitted for use in lactating animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, ATCVet code: QJ01BA90

5.1 Pharmacodynamic properties

Florfenicol is a synthetic broad spectrum antibiotic effective against most Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol acts by inhibiting protein synthesis at the ribosomal level and is bacteriostatic. Laboratory tests have shown that florfenicol is active against the most commonly isolated bacterial pathogens involved in bovine respiratory disease which include *Mannheimia haemolytica, Pasteurella multocida and Histophilus somni*.
Florfenicol is considered to be a bacteriostatic agent, but *in vitro* studies of florfenicol demonstrated bactericidal activity against *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni*.

Acquired resistance to florfenicol is mediated by efflux pump resistance associated with a *floR* gene. Such resistance has not yet been identified in the target pathogens except for *Pasteurella multocida*. Cross resistance with chloramphenicol can occur. Resistance to florfenicol and other antimicrobials has been identified in the food-borne pathogen *Salmonella typhimurium.*

5.2 Pharmacokinetic properties

Intramuscular administration at the recommended dose of 20 mg/kg maintains efficacious blood levels in cattle for 48 hours. Maximum mean plasma concentration (Cmax) of 3.86 µg/ml occurs at 5 hours (Tmax), after dosing. The mean plasma concentration 24 hours after dosing was 1.56 µg/ml.

The harmonic mean elimination half life was 18.8 hours.

After subcutaneous administration of the recommended dose of 40 mg florfenicol/kg b.w., maximum plasma concentration (Cmax) of approximately 3.5 µg/ml occurs approximately 7.0 hours (Tmax) after dosing. The mean plasma concentration 24 hours after dosing is approximately 2 µg/ml.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dimethyl sulfoxide
Propylene glycol
Macrogol 400

6.2 Incompatibilities

In the absence of incompatibility studies, this veterinary medicinal product should not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after first opening the immediate container: 28 days

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

50, 100 and 250 ml Type I amber glass bottle closed with a bromobutyl rubber stopper and aluminium seal.
1 bottle (50 ml) in cardboard box.
1 bottle (100 ml) in cardboard box.
1 bottle (250 ml) in cardboard box.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Gosmore Ltd,
9 Pitch and Pay Lane,
Sneyd Park,
Bristol BS9 1NH,
UK.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10809/003/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

3rd September 2010

10 DATE OF REVISION OF THE TEXT