[Version 9,03/2022]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxycomplex NS Solution for Injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Oxytetracycline Hydrochloride equivalent to Oxytetracycline	100 mg
Flunixin Meglumine equivalent to Flunixin	20 mg

Excipients:

Qualitative composition of excipients and other constituents
Magnesium Chloride
N-methyl pyrrolidone
Monoethanolamine
Sodium Formaldehyde Sulfoxylate
Water for injection

A clear yellow to amber liquid.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For the control and treatment of infectious diseases of cattle caused by or associated with organisms sensitive to oxytetracycline, where concurrent analgesic, anti-inflammatory, anti-endotoxic or antipyretic therapy is desired.

The veterinary medicinal product is especially indicated for the treatment of respiratory disease (particularly that associated with *Pasteurella* infection) and acute mastitis (in conjunction with appropriate therapy).

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use in horses or donkeys.

Do not exceed the stated dose or duration of treatment.

Do not administer other NSAIDs concurrently or within 24 hours of each other.

Use is contra-indicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding or where there is evidence of a blood dyscrasia.

3.4 Special warnings

Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs to produce an increase in non-bound pharmacologically active concentrations, which can lead to toxic effects.

Use in any animal less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided animals may require a reduced dosage and careful clinical management.

Avoid use in any dehydrated, hypovolaemic or hypersensitive animal as there is a potential risk of renal toxicity.

It is preferable that flunixin is not administered to animals undergoing general anaesthesia until fully recovered.

Concurrent administration of methoxyflurane anaesthesia or other potentially nephrotoxic drugs should be avoided.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

The veterinary medicinal product should only be used in individual animals.

The feeding of waste milk containing residues of oxytetracycline to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

3.6 Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Intestinal disorder (gastrointestinal ulceration)

Prolonged use of NSAIDs, including flunixin, may predispose or lead to gastrointestinal ulceration.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation..

3.8 Interactions with other medicinal products and other forms of interaction

The veterinary medicinal product may potentiate the effects of Warfarin and related drugs.

Because of their common mode of action, flunixin may be potentiated by other NSAIDs which act by interfering with prostaglandin synthesis.

Where other products are to be administered concurrently with the veterinary medicinal product, drug compatibility should be carefully monitored.

Corticosteroids should not be used concurrently with this product.

3.9 Administration routes and dosage

To ensure a correct dosage body weight should be determined as accurately as possible.

By intravenous or deep intramuscular injection at a rate of 1 ml of the veterinary medicinal product per 10 kg bodyweight (equivalent to 10 mg oxytetracycline and 2 mg flunixin per kg bodyweight) daily for up to 5 days.

Do not inject more than 20 ml intramuscularly at a single site. Where the dose exceeds 20 ml it should be divided between two or more sites, as appropriate.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Overdosing by intramuscular injection may give rise to swellings at the site of injection. Treatment should be symptomatic.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 28 days.
Milk: 5 days.
Where cows are milked twice daily milk may be taken for human consumption from the 11th milking following the last treatment.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01AA56

4.2 Pharmacodynamics

The veterinary medicinal product contains two active ingredients: oxytetracycline hydrochloride and flunixin meglumine.

Oxytetracycline is a broad spectrum antibiotic of the tetracycline group. The drug was discovered in the 1950s. It is derived from the soil mould *Actinomyces rimosus.* Oxytetracycline is bacteriostatic at therapeutic concentrations but may be bactericidal at higher concentrations. The mode of action of oxytetracycline and other tetracyclines involves interference with protein and RNA synthesis in the growing and reproducing bacterial cell.

Flunixin is a non-steroidal anti-inflammatory drug (NSAID) which acts by interfering with the arachidonic acid pathway of prostaglandin synthesis. NSAIDs are suitable drugs for use in combination with bacteriostatic antibiotics, since they do not have the sort of immunosuppressive effect which may be associated with corticosteroid anti-inflammatory drugs.

4.3 Pharmacokinetics

With regard to the pharmacokinetics of the oxytetracycline component, elimination following intravenous injection is broadly exponential in character. When injected intramuscular Cmax is reached 4 - 6 hours after injection, after which the concentration again declines exponentially. There is some degree of "loading" following the initial intramuscular injection, with the serum concentration of oxytetracycline 24 hours after the second intramuscular injection being slightly higher than the concentration 24 hours after the first. The effect, however, does not persist, with a plateau being reached following the second intramuscular injection.

The pharmacokinetic profile of the flunixin component is somewhat different in that a series of minor peaks occur following injection by either the intravenous or intramuscular route. This is attributed to enterohepatic recirculation of the drug. As was the case with the oxytetracycline component, there is some evidence of "loading" following the first intramuscular injection reaching a plateau after the second intramuscular injection.

Environmental properties

Flunixin is toxic to avian scavengers although foreseen low exposure leads to low risk.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25°C.
Protect from light.

5.4 Nature and composition of immediate packaging

100 ml Type II amber glass vials fitted with bromobutyl rubber stoppers and sealed with plain aluminium caps.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA 22033/042/001

8. DATE OF FIRST AUTHORISATION

10 June 1994

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).