

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10126/063/001**
Case No: 7005496

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Bimeda Chemicals

Broomhill Road, Tallaght, Dublin 24., Ireland

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Oxycomplex NS Solution for Injection

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **09/06/2009**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

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 100 mg
equivalent to Oxytetracycline

Flunixin Meglumine 20 mg
equivalent to Flunixin

Excipients

Sodium Formaldehyde 2 mg
Sulfoxylate

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the 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.

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

4.3 Contraindications

Not suitable for animals with known hypersensitivity to the active ingredient.

Not suitable for 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.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

Oxycomplex NS is safe for use in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Oxycomplex NS 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 Oxycomplex NS, drug capability should be carefully monitored.

Corticosteroids should not be used concurrently with this product.

4.9 Amounts to be administered and administration route

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 Oxycomplex NS 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 mls intramuscularly at a single site. Where the dose exceeds 20 mls it should be divided between two or more sites, as appropriate.

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

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

4.11 Withdrawal Period(s)

Meat: Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days following the last treatment.

Milk: Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from cows only after 10 milkings (5 days) following the last treatment.

Where cows are milked twice daily milk may be taken for human consumption from the 11th milking following the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, oxytetracycline, combinations.
ATCvet code: QJ01AA56

5.1 Pharmacodynamic properties

Oxycomplex NS 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 1950's. 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. NSAID's 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.

5.2 Pharmacokinetic properties

With regard to the pharmacokinetics of the oxytetracycline component, elimination following intravenous injection is broadly exponential in character. When injected intramuscular C_{max} 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Chloride
N-methyl pyrrolidone
Monoethanolamine
Sodium Formaldehyde Sulfoxylate
Water for Injection

6.2 Incompatibilities

None.

6.3 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.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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

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

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

7 MARKETING AUTHORISATION HOLDER

Bimeda Chemicals Ltd.,
Broomhill Road,
Tallaght,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10126/063/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

9th June 2009