Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Interject 15% Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance
Oxytetracycline Hydrochloride Ph. Eur. 150 mg

Excipients
Dimethylacetamide q.s to 1 ml (Approx. 48 %)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep and pigs.

4.2 Indications for use, specifying the target species

Interject 15% is recommended in the treatment of a wide range of common systemic, respiratory and local infections caused by, or associated with, organisms sensitive to Oxytetracycline.

4.3 Contraindications

Do not use in sheep producing milk for human consumption.
Do not use in animals with known hypersensitivity to the active ingredient.
Do not administer intravenously.
Do not use in horses, dogs and cats.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use. This product contains dimethylacetamide (DMAC) and care should be taken to prevent absorption through the skin.
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.

4.6 Adverse reactions (frequency and seriousness)

Interject 15% is well tolerated but transient local reactions may occur at the injection site.
Use of tetracycline during the period of tooth development, including late pregnancy, may lead to tooth discoloration.
Occasional allergic reactions occur but these are rare.

4.7 Use during pregnancy, lactation or lay

Use of tetracycline during the period of tooth development, including late pregnancy, may lead to tooth discolouration.

4.8 Interaction with other medicinal products and other forms of interaction

Interject 15% should not be diluted or mixed with solutions of calcium salts

4.9 Amounts to be administered and administration route

For intramuscular use only.
The recommended dosage is 5 mg per kg or 3.5 ml per 100 kg bodyweight.

SPECIES	DOSE (ml) / kg bodyweight
Cow	3.5 ml / 100 kg
Calf	1.75 ml / 50 kg
Sheep	1.0 ml / 25 kg
Lamb	0.5 ml / 10 kg
Piglet	0.25 ml / 5 kg

These are average recommendations. The period of treatment should extend from 3-5 days, depending on the severity of the condition being treated.
If the injection volume exceeds 25 ml, divide the dose and administer at two separate injection sites.
To ensure a correct dosage bodyweight should be determined as accurately as possible.

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

Do not exceed the stated dose.

4.11 Withdrawal Period(s)

Milk should not be used for human consumption during treatment. Milk for human consumption may be taken after 96 hours (that is, from the 9th milking in cows milked twice daily) after the last treatment. Do not use in sheep producing milk for human consumption.
Animals should not be slaughtered for human consumption during treatment. Animals may be slaughtered for human consumption after 28 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QJ01AA06
Pharmacotherapeutic Group: Antibacterial for systemic use, tetracyclines.

5.1 Pharmacodynamic properties

Oxytetracycline is a bacteriostatic antibiotic with a broad range of antibacterial activity. Oxytetracycline is rapidly absorbed from the injection site with peak plasma levels within 2 hours. Therapeutic plasma levels are maintained for 24 hours post treatment.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Chloride
Water for Injection
Sodium Formaldehyde Sulfoxylate
Monoethanolamine
Dimethylacetamide

6.2 Incompatibilities

The product should not be diluted or mixed with solutions of calcium salts.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life following opening of the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25 ^{0}C.
Do not freeze.

6.5 Nature and composition of immediate packaging

100 ml amber, type II glass vial, closed with a grey nitryl stopper and aluminium seal.
Presentations: 12 x 100 ml and 25 x 100 ml.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Interchem (Ireland) Ltd.,
29 Cookstown Industrial Estate,
Dublin 24,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10555/006/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20th March 2008

10 DATE OF REVISION OF THE TEXT

January 2012.