Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bactidiaryl Oral Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100g contains :

Active substances:
Tetracycline hydrochloride 0.25 g
Neomycin sulphate 500 000 IU

Excipients:
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Calves.

4.2 Indications for use, specifying the target species

Treatment of infections caused by strains sensitive to tetracycline and/or neomycin.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

None.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Not relevant.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For oral administration.

Bactidiaryl may be administered alone or combined with milk. Dilute with tepid water and administer orally. It is recommended that milk is withdrawn at the start of the treatment.

Calves: 1 pack per 50 kg bw, diluted in 1 or 2 litres of tepid water every 12 hours or ½ pack diluted in one litre of water twice in the morning and twice in the afternoon.
The treatment should be repeated for 2 to 3 days.

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

None known.

4.11 Withdrawal period(s)

Meat: 8 days.Milk: Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiinfectant for systemic use; tetracyclines, combinations with other antibacterials.
ATCvet code: QJ01RA90
Bactidiaryl is a palatable powder containing anti-infectious elements, proteins, lipids, glucids and electrolytes.Tetracycline and neomycin are a broad-spectrum antibiotic combination active against aerobic and anaerobic gram-positive and gram-negative bacteria.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Milk aroma No 88 396
Sodium Cyclamate.
Ethyl Vanillina USP
Banana aroma givauclan
Sodium Chloride
Maize Starch
Carob flour
Carrot flour
Soya flour
Sodium Alginate
Rice flour
Primelka S 1902 CAnhydrous Dextrose

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Aluminium foil pack containing 100g of an oral powder, 50 sachets per box.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
12 Northbrook Road
Ranelagh
Dublin 6
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10983/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1988
Date of last renewal: 30th September 2008

10 DATE OF REVISION OF THE TEXT

August 2019