1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bactidiaryl Oral Powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g contains:

Active substances:

Tetracycline hydrochloride 0.25 g
Neomycin sulphate 500 000 IU

Excipients:

Qualitative composition of excipients and other constituents
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

Oral powder.

3. CLINICAL INFORMATION

3.1 Target species

Calves.

3.2 Indications for use for each target species

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

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

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

The veterinary medicinal product 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 It is recommended that milk is withdrawn at the start of the treatment.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 bodyweight (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.

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

None known.

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: 8 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01RA90

4.2 Pharmacodynamics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25 ºC.

5.4 Nature and composition of immediate packaging

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

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

Vetoquinol Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10983/006/001

8. DATE OF FIRST AUTHORISATION

01/10/1988

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

03/03/2026

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).