1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sulpha No. 2 Powder for Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:
Active substance
Sulfadimidine 990.1 mg/g.

Excipients:

Qualitative composition of excipients and other constituents
Colloidal Anhydrous Silica

3. CLINICAL INFORMATION

3.1 Target species

Calves.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for use in calves as an anti-bacterial agent effective against sulfonamide sensitive organisms.

3.3 Contraindications

Do not use in animals with serious liver or renal disturbances.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not treat for longer than 7 days.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Adequate water intake for animals being treated is essential to avoid the occurrence of crystaluria. 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:

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 immediate packaging 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. The veterinary medicinal product should be mixed with milk or water.
To ensure a correct dosage, body weight should be determinated as accurately as possible.
As an initial dose, sulfadimidine 200 mg/kg bodyweight, equivalent to 2 g veterinary medicinal product per 10 kg bodyweight, is recommended.
As a maintenance dose, sulfadimidine 100 mg/kg bodyweight, equivalent to 1 g veterinary medicinal product per 10 kg bodyweight daily for 5-7 days is recommended.

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: 28 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01EQ03

4.2 Pharmacodynamics

Sulfadimidine is a member of the sulfonamide group of drugs. The activity of the sulfonamides is bacteriostatic and broad spectrum.
The mechanism of action involves competitive inhibition with PABA in bacterial metabolism thereby blocking functional folic acid synthesis and ultimately leading to decreased purine

production, which effectively decreases nucleic acid synthesis. Sulfonamide – sensitive bacteria are unable to utilise a pre-formed source of folic acid. Bacteria, which do not require folic acid for growth or can use pre-formed folic acid are resistant to the anti-bacterial actions of sulfonamides. Conversely, animal cells have an absolute requirement for pre-formed folic acid and therefore, sulfonamides do not cause concomitant effects in the host.

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.
Shelf-life after first opening the immediate packaging: 24 hours.

5.3 Special precautions for storage

Store in a dry place.
Do not store above 25 °C.
Protect from light.

5.4 Nature and composition of immediate packaging

25 g Foil/paper sachet.
40 g paper /12 g polyethylene/7µ foil / 25 g polyethylene.

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

Chanelle Pharmaceuticals Manufacturing Ltd.,

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10987/018/001

8. DATE OF FIRST AUTHORISATION

01/10/1988

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

11/07/2025

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).