1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ampisol 2 g , powder for solution for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains

Active Substance:

Ampicillin (as ampicillin sodium Ph. Eur) 2g

After reconstitution with 8 ml of Water for Injection, 1 ml of solution contains 200 mg of ampicillin.

White crystalline powder.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

For the treatment and control of respiratory tract, alimentary tract and urogenital tract infections.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level. Use of the product should be in accordance with official, national and regional antimicrobial policies. Avoid introduction of contamination during use. Use immediately after reconstitution.

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

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reaction with cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations. Handle this product with care to avoid exposure. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this

warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and may require urgent medical attention.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Undetermined frequency (cannot be estimated from the available data).	Hypersensitivity and anaphylactic reaction

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 its local representative 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

Pregnancy and lactation

The use is not recommended during pregnancy or lactation

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration with other anti-infectives and antibiotics should be avoided.

3.9 Administration routes and dosage

Add 8 ml of Water for Injection to obtain 10 ml of solution.
6 mg to 22 mg per kg bodyweight by intramuscular or intravenous injection. The higher levels are generally required when treating Gram negative infections and young animals. Treatment should be repeated at 12 to 24 hour intervals.

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

Not applicable.

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: 6 months.
Not authorised for use in animals producing milk for human consumption.

4 PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01CA01

4.2 Pharmacodynamics

Ampicillin is a broad spectrum bactericidal antibiotic, active against Gram +ve and Gram -ve organisms. Ampicillin like all B-lactam antibiotics is bactericidal. The cell walls of bacteria are essential for their normal growth and development. Ampicillin interferes with cell wall development leading to rupture, lysis and cell death.

5 PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: use immediately.

5.3 Special precautions for storage

Do not store above 25°C.

5.4 Nature and composition of immediate packaging

10ml type II Vials (Clear) sealed with bromobutyl rubber bungs (grey) and overseals (aluminium). Twelve glass vials in a cardboard 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

Acravet Ltd.

7 MARKETING AUTHORISATION NUMBER(S)

VPA10793/002/001.

8. DATE OF FIRST AUTHORISATION

18/12/1991.

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

13 November 2023

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).