1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cartrophen Vet 100 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance:
Pentosan polysulfate sodium 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol	0.01 ml
Disodium phosphate dodecahydrate	
Sodium dihydrogen phosphate dihydrate	
Sodium hydroxide	
Hydrochloric acid	
Water for injections	

Clear, colourless to slightly yellow, aqueous solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For the treatment of lameness and pain of osteoarthritis (non-infectious arthrosis) and related musculoskeletal disorders by therapeutic activity on the underlying pathological processes (disease modifying osteoarthritis drug) in the dog.

3.3 Contraindications

Pentosan polysulfate sodium is contra-indicated for the treatment of septic arthritis. In this case, appropriate antimicrobial therapy should be instigated.
Do not use in dogs with uncontrolled bleeding, trauma, infection, advanced liver or kidney impairment and cancer, especially haemangiosarcoma.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Do not exceed the standard dose. Increasing the recommended dose may result in exacerbation of stiffness and discomfort.

The product is not intended for use in arthritides of immunological origin (e.g. rheumatoid arthritis).

It has been reported that a dog which had suffered pulmonary lacerations twelve months previously had severe pulmonary bleeding after an injection of the product. Use with caution in dogs with a history of pulmonary lacerations.

Because of the fibrinolytic action of pentosan polysulfate sodium, the possibility of internal bleeding from a tumour or vascular abnormality should be considered and appropriate therapeutic action taken. It is recommended that the PCV and capillary filling time should be monitored.

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

Care should be taken to avoid accidental self-injection. Wash splashes from eyes and skin immediately with water. Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Rare (1 to 10 animals / 10,000 animals treated):	Injection site reaction[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[2], Depression[3], lethargy[3]

[1] Occur within 24 hours in an apparent healthy animal. Treatment should be discontinued, and symptomatic relief given.
[2] Immediately after injection. Such dogs generally require no medical treatment and make an uneventful recovery. Further treatment with pentosan polysulfate is not recommended.
[3] Mild and lasting up to 24 hours.

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

Pregnancy:
The safety of the veterinary medicinal product has not been established during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

NSAIDs and in particular aspirin should not be used in combination with pentosan polysulfate sodium as they may affect thrombocyte adhesion and potentiate the anticoagulant activity of the product. Corticosteroids have been shown to be antagonistic to a number of actions of pentosan polysulfate sodium. Furthermore, use of anti-inflammatory drugs may result in a premature increase in the dog's activity, which may interfere with the analgesic and regenerative effects of the veterinary medicinal product.

Do not use concurrently with steroids or non-steroidal anti-inflammatory drugs, including aspirin and phenylbutazone or within 24 hours of such administration. Do not use in conjunction with heparin and other anti-clotting agents.

3.9 Administration routes and dosage

Subcutaneous use.
3 mg pentosan polysulfate sodium / kg bodyweight (equivalent to 0.3 ml/10kg bodyweight) on four occasions, with an interval of 5-7 days.
Administer by aseptic subcutaneous injection only. For accurate dosing use must be made of an insulin-type syringe.

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

At the recommended dose and duration of treatment, side effects are very rare (refer to 3.6).

At three times the recommended dose a transient increase in bleeding time of about 3 to 4 hours duration has been observed. Repeated daily overdoses of five times the recommended dose or more resulted in anorexia and depression, which were reversible upon withdrawal of the drug.

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

For administration by a veterinarian or under their direct supervision.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AX90

4.2 Pharmacodynamics

The product contains Pentosan Polysulfate Sodium, a semi-synthetic polymer with a mean molecular weight of 4000 Daltons, with anti-inflammatory activity, and modulating effects on cartilage and synovial metabolism and an affinity for cartilage. By binding to cartilage the polymer reduces breakdown and stimulates new synthesis. In addition, it has fibrinolytic, lipolytic and mild anti-coagulant activities. Pentosan polysulfate sodium has an effect on blood coagulation due to its heparin-like structure and fibrinolytic activity that lasts for up to 6-8 hours after administration. This is of no clinical significance in the normal dog.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

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: 3 months.

5.3 Special precautions for storage

Store below 25°C.
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

10 ml Ph.Eur. Type I clear glass vial fitted with a 20 mm bromobutyl rubber stopper and closed by a plastic flip off seal attached to an aluminium seal.

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

Maperath Herbal Ltd

7. MARKETING AUTHORISATION NUMBER(S)

VPA 22748/001/001

8. DATE OF FIRST AUTHORISATION

01 October 1991

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

15 January 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).