Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Cartrophen Vet 100mg/ml Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance
Pentosan Polysulphate Sodium 100mg

Excipient
Benzyl Alcohol 0.01ml

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Solution for Injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the 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.

4.3 Contraindications

Pentosan polysulphate 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 polysulphate 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.

4.6 Adverse reactions (frequency and seriousness)

Rarely, reaction to the injection may occur within 24 hours in an apparently healthy animal. In these circumstances treatment should be discontinued and symptomatic relief given.

Experience indicates that in very rare cases, dogs may vomit immediately after injection with pentosan polysulphate. Such dogs generally require no medical treatment and make an uneventful recovery. Further treatment with pentosan polysulphate is not recommended.

A further very rare side effect following administration of pentosan polysulphate sodium in dogs is an apparent mild depression and lethargy lasting up to 24 hours.

4.7 Use during pregnancy, lactation or lay

The safety of the product in the pregnant bitch has not been studied.

4.8 Interaction with other medicinal products and other forms of interactions

NSAIDs and in particular aspirin should not be used in combination with pentosan polysulphate 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 polysulphate 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 Cartrophen Vet.

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.

4.9 Amounts to be administered and administration route

3 mg pentosan polysulphate 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.

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

At the recommended dose and duration of treatment, side effects are very rare (refer to 4.6).

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.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The product contains Pentosan Polysulphate 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 polysulphate 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Disodium phosphate dodecahydrate
Sodium dihydrogen phosphate dihydrate
Sodium hydroxide
Hydrochloric acid
Water for injection

6.2 Major incompatibilities

None known.

6.3 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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

A clear, colourless to slightly yellow, aqueous solution contained in a 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.

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

Maperath Herbal Limited
Barronstown
Rathkenny
Navan
Meath
C15 T638
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22748/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1991
Date of last renewal: 01 October 2006

10 DATE OF REVISION OF THE TEXT

March 2019