PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cartrophen Vet 100 mg/ml Solution for Injection for Dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1ml contains: Pentosan polysulfate sodium 100mg and benzyl alcohol 10.45mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For the treatment of lameness and pain of degenerative joint disease/osteoarthrosis (non-infectious arthrosis) in the skeletally mature dog.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous injection

Administer by aseptic subcutaneous injection.

Dose: 3mg/kg bodyweight every 5-7 days on four occasions.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

Following withdrawal of first dose, use the product within 3 months. Discard unused material.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution Category]

POM-V

For animal treatment only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Arthropharm Europe Limited
4 Dock Street
Warrenpoint
BT34 3LZ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15519/4001

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cartrophen Vet 100 mg/ml Solution for Injection for Dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Pentosan polysulfate sodium

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE(S) OF ADMINISTRATION

For subcutaneous use.

5. WITHDRAWAL PERIOD

N/A

6. BATCH NUMBER

7. EXPIRY DATE

Shelf-life after first opening the immediate packaging 3 months.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

POM-V

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

4 Dock Street
Warrenpoint BT34
3LZ
Northern Ireland
Phone no: +44(0) 2380171055

Manufacturing authorisation holders responsible for batch release:

Eurovet Animal Health B.V.
Handelsweg 25
5531AE Bladel
The Netherlands
Phone : +31 (0) 497544300

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cartrophen Vet 100 mg/ml Solution for Injection for Dogs

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

A clear colorless to slightly yellow aqueous solution for subcutaneous administration.
Each 1ml contains: Pentosan polysulfate sodium 100mg and benzyl alcohol 10.45mg.

4. INDICATION(S)

For the treatment of lameness and pain of degenerative joint disease/osteoarthrosis (non-infectious arthrosis) in the skeletally mature dog.

5. CONTRAINDICATIONS

Do not use for the treatment of septic arthritis. In this case, appropriate antimicrobial therapy should be instigated.
Do not use in dogs with advanced liver or kidney impairment, or evidence of infection.
Do not use in dogs with blood disorders, coagulation disorders, bleeding or malignancy (especially haemangiosarcoma). Pentosan polysulfate has an anticoagulant effect.
Do not use during the peri-operative period.

Do not use in the skeletally immature dog (i.e. dogs whose long bone growth plates have not closed).

6. ADVERSE REACTIONS

Emesis, diarrhoea, lethargy and anorexia have been reported following the use of pentosan polysulfate. These signs may be the result of a hypersensitivity reaction and may require appropriate symptomatic treatment including antihistamine administration.
Administration of the product at recommended dose rates results in increases of activated partial thromboplastin time (aPTT) and thrombin time (TT) which may persist for up to 24 hours after administration in healthy dogs. This very rarely results in clinical effects, but because of the fibrinolytic action of pentosan polysulfate sodium, the possibility of internal bleeding from a tumor or vascular abnormality should be considered if signs develop. It is recommended that the animal should be monitored for signs of blood loss and treated appropriately
Bleeding disorders such as nasal bleeding, hemorrhagic diarrhoea and haematomas have been reported.
Local reactions such as a transient swelling have been observed post injection.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dog

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage: 3mg pentosan polysulfate sodium/kg bodyweight on four occasions, with an interval of 5-7 days between each administration.

Administration: By aseptic subcutaneous injection only of 0.3ml/10kg of bodyweight. An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.
Each case should be assessed individually by the veterinarian and an appropriate treatment program determined.

9. ADVICE ON CORRECT ADMINISTRATION

The product should not be administered in the same syringe with other substances.

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Keep the container in the outer carton in order to protect from light. Following withdrawal of first dose, use the product within 3 months. Discard unused material.

When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

A clinical effect may not be observed until after the second injection of the course of treatment.

Dogs should be weighed prior to administration to ensure accurate dosing.

Use with caution in dogs with history of pulmonary lacerations. Caution is also recommended in cases of hepatic impairment.
Do not exceed the standard dose. Increasing the recommended dose may result in exacerbation of stiffness and discomfort.
No more than 3 courses of 4 injections should be administered in a 12 month period.

Laboratory studies in rabbits showed embryo toxic effects associated with a primary effect on the parent at repeated daily doses 2.5 times the recommended therapeutic dose.
The safety of the product in the pregnant bitch has not been studied, therefore use is not recommended in these circumstances.
The product should not be used at the time of parturition due to its anticoagulant effects.
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 therapeutic activity of the product.
Do not use concurrently with steroids or non-steroidal anti-inflammatory drugs, including aspirin and phenylbutazone.
Do not use concurrently with heparin, warfarin or other anti-coagulants.

Overdose: Repeated daily overdoses of five times the recommended dose or more results in anorexia and depression, which are reversible upon withdrawal of the drug. At overdose there may be hepatocellular damage and an associated, dose- dependent, elevation in ALT. Increases in aPTT and TT are dose-dependent. At repeated doses greater than five times that recommended, these increases may persist beyond 1 week after administration in healthy dogs. Signs associated with these defects may include bleeding into the gastro-intestinal tract, body cavities and ecchymoses. At repeated doses greater than ten times that recommended there may be fatality as a result of gastro-intestinal haemorrhage. If overdose occurs dogs should be hospitalized and observed and supportive therapy provided as deemed necessary by the veterinarian.
User warnings: Care should be taken to avoid accidental self-injection. In the event of accidental injection, seek medical advice immediately and show the package leaflet or label to the physician. Wash splashes from eyes and skin immediately with water. Wash hands after use.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

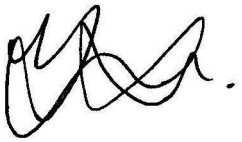
October 2022

15. OTHER INFORMATION

POM - V

Vm 15519/4001

Pack size: multidose vials of 10ml



Approved: 14 October 2022