PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anarthron 100 mg/mL solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Pentosan polysulfate sodium 100 mg/ml

3. PACKAGE SIZE

10 ml

4. TARGET SPECIES

Dog

5. INDICATIONS

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

6. ROUTES OF ADMINISTRATION

For subcutaneous use.

7. WITHDRAWAL PERIODS

Not applicable

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 3 months.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Keep the vial in the outer carton in order to protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Arthropharm (NI) Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 62860/5001(GB)

Vm 62860/3001 (NI)

15. BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {vial label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anarthron 100 mg/mL solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Pentosan polysulfate sodium 100 mg/ml

3. TARGET SPECIES

Dog

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp.

Once broached use within 3 months.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C

Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Arthropharm (NI) Limited

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Anarthron 100 mg/mL solution for injection for dogs

2. Composition

Each ml contains:

Active substance
Pentosan polysulfate sodium 100 mg

Excipient
Benzyl Alcohol 0.01 ml

A clear, colourless pale yellow solution.

3. Target species

Dog

4. Indications for use

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 in 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 sodium 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. Special warnings

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 embryotoxic 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. Do not use after the expiry date printed on the label and carton after EXP.

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

7. Adverse events

Dog

Very rare (<1 animal / 10 000 animals treated, including isolated reports)	Emesis[1,2], diarrhoea[1,2] Lethargy[1,2], anorexia[1,2] Hypersensitivity reaction[2] Prolonged activated partial thrombin time (APTT)[3], prolonged thrombin time (TT)[3] Injection site reaction, injection site swelling[4]
Undetermined frequency (cannot be estimated from the available data):	Bleeding disorder (e.g. nasal bleeding, haemorrhagic diarrhoea, haematoma)

[1] Due to a hypersensitivity reaction.
[2] May require appropriate symptomatic treatment, including antihistamine administration.
[3] 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 tumour 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.
[4] Transient.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website:https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail:adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Dosage: 3mg pentosan polysulfate sodium/kg bodyweight (equivalent to 0.3ml/10kg 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.

9. Advice on correct administration

10. Withdrawal periods

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

Keep the vial in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 62860/5001(GB)

Vm 62860/3001 (NI)

10 ml vial.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Arthropharm (NI) Limited
44 Church Street
Warrenpoint
Newry
Northern Ireland
BT34 3NH
Phone: +353 1 841 5533
Email: info@arthropharmeu.com

Manufacturer responsible for batch release:

Eurovet Animal Health B.V.
Handelsweg 25
5531AE Bladel
The Netherlands

17. Other information

POM-V

Gavin Hall
Approved: 09 September 2026