SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anarthron 100mg/mL solution for injection for dogs

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/ml
Disodium phosphate dodecahydrate	
Sodium dihydrogen phosphate dihydrate	
Sodium hydroxide	
Hydrochloric acid	
Water for injection	

Solution for injection.

A clear, colourless pale yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Dog

3.2 Indications for use for each target species

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

3.3 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).

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

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

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 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:

Laboratory studies in rabbits showed embryotoxic effects associated with a primary effect on the parent at repeated daily doses 2.5 times the recommended 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.

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 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.

3.9 Administration routes and dosage

Subcutaneous use.

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.

Each case should be assessed individually by the veterinarian and an appropriate treatment program determined.

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

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 hospitalised and observed and supportive therapy provided as deemed necessary by the veterinarian.

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 only by a veterinarian.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICALINFORMATION

4.1 ATCvetcode: QM01AX90

4.2 Pharmacodynamics

The product contains Pentosan Polysulfate Sodium (NaPPS), a semi-synthetic polymer with a mean molecular weight of 4000 Daltons.

In a model of osteoarthritis in dogs, when NaPPS was administered at similar to therapeutic doses, levels of metalloproteinases in cartilage were reduced and levels of tissue inhibitor of metalloproteinase (TIMP) increased, thereby preserving proteoglycan content and protecting cartilage matrix from degradation.

In dogs with osteoarthritis administration of NaPPS caused fibrinolysis, lipolysis and decreased platelet aggregability.

In *in vitro* studies and *in vivo* studies in laboratory species using doses above those proposed for therapeutic use, NaPPS suppressed levels of anti-inflammatory mediators and stimulated hyaluron synthesis from fibroblasts.

4.3 Pharmacokinetics

Absorption: In the dog, a peak plasma concentration of 7.40 pentosan polysulfate sodium/mL is achieved 15 minutes after subcutaneous administration.
Distribution: Pentosan polysulfate sodium binds many plasma proteins with a variable strength of association and dissociation resulting in a complex equilibrium between bound and unbound drug. Pentosan polysulfate sodium is concentrated in the liver and kidneys and reticuloendothelial system. Low levels occur in connective tissue and muscle. In studies carried out with rabbits, it has been shown that therapeutic concentrations of the active ingredient remain in the joint cartilage for 4-5 days after administration. The volume of distribution in dogs is 0.43L.
Biotransformation: Desulfation of pentosan polysulfate sodium occurs in the hepato-reticulo-endothelial system, the liver being the main site of activity. Depolymerisation may also occur in the kidney.
Elimination: The product is eliminated with a half life of approximately 3 hours in the dog. Forty eight hours after injection approximately 70% of the dose administered is eliminated via urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

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

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

5.4 Nature and composition of immediate packaging

A 10 ml Ph.Eur. Type 1 clear glass vial fitted with a 20 mm rubber stopper Ph.Eur and closed by a plastic flip off seal attached to an aluminium seal.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Arthropharm (NI) Limited

7. MARKETING AUTHORISATION NUMBER

Vm 62860/5001 (GB)
Vm 62860/3001 (NI)

8. DATE OF FIRST AUTHORISATION

01 May 2007

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

September 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 09 September 2026