Revised: May 2024
MA split from NI MA following AN:02164/2023

ANARTHRON LABEL TEXT – February 2013

NOTE: This label text is prepared in accordance with the CMD(v) annotated QRD template (Version 8, 10/2012). Text shaded in grey indicates that stated text will not appear on the final printed material.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anarthron 100mg/mL solution for injection for dogs
Pentosan polysulfate sodium

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

100mg/mL

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

10ml

4. ROUTE(S) OF ADMINISTRATION

For subcutaneous use.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

BN:

7. EXPIRY DATE

EXP:

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

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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ANARTHRON CARTON TEXT – FEBRUARY 2013

NOTE: This carton text is prepared in accordance with the CMD(v) annotated QRD template (Version 8, 10/2012). Text shaded in grey indicates that stated text will not appear on the final printed material.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anarthron 100mg/mL solution for injection for dogs.
Pentosan polysulfate sodium

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Pentosan polysulfate sodium 100mg/mL

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10ml

5. TARGET SPECIES

Dog

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For subcutaneous use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

Use by: _____/____/_____

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11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep container in the outer carton in order to protect from light. Once broached, use within 3 months.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNSUED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

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

For animal treatment only

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

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Arthropharm Europe Limited
50 Bedford Street
Belfast BT2 7FW
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15519/3000

17. MANUFACTURER'S BATCH NUMBER

BN

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ANARTHRON PACKAGE LEAFLET TEXT – FEBRUARY 2013

NOTE: This package leaflet text is prepared in accordance with the CMD(v) annotated QRD template (Version 8, 10/2012). Text shaded in grey indicates that stated text will not appear on the final printed material.

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

Marketing authorisation holder:
Arthropharm Europe Limited
50 Bedford Street
Belfast BT2 7FW
Northern Ireland
Phone: +353 1 841 5533

Manufacturing authorisations holders responsible for batch release:
Eurovet Animal Health B.V.
Handelsweg 25
5531AE Bladel
The Netherlands

Forte Healthcare Limited
Cougar Lane
Naul, Co. Dublin
Ireland

10. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anarthron 100mg/mL solution for injection for dogs

11. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A clear colourless to slightly yellow aqueous solution for subcutaneous administration.
Each 1ml contains: Pentosan polysulfate sodium 100mg and benzyl alcohol 0.01ml

12. INDICATION(S)

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

13. CONTRAINDICATIONS

The product is contra-indicated 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).

14. 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 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

Bleeding disorders such as nasal bleeding, haemorrhagic diarrhoea and haematomas have been reported.

Local reactions such as a transient swelling have been observed post injection.

15. TARGET SPECIES

Dog

16. 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.

17. ADVICE ON CORRECT ADMINISTRATION

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

18. WITHDRAWAL PERIOD

Not applicable

19. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep 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 insert, the date on which the product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the carton.

Keep out of the reach of children.

20. SPECIAL WARNING(S), IF NECESSARY

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.

21. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNSUED PRODUCTS 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.

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22. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

23. OTHER INFORMATION

Pack size: carton containing one multidose vial of 10mL

Approved 18 May 2024

Gavin Hall