SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Osteopen 100 mg/ml Solution for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Pentosan Polysulphate 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 E1519	10.45 mg
Disodium phosphate dodecahydrate	
Sodium dihydrogen phosphate dihydrate	
Sodium hydroxide (for pH adjustment)	
Hydrochloric acid (for pH adjustment)	
Water for injections	

A clear pale yellow aqueous solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For the treatment of lameness and pain of degenerative joint disease/osteoarthritis (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 cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in the skeletally immature dog (i.e. dogs whose long bone growth plates have not closed).
Do not use in dogs with blood disorders, coagulation disorders, bleeding, trauma or malignancy (especially haemangiosarcoma) or during the peri-operative period within 6 – 8 hours of surgery as pentosan polysulphate has an anticoagulant effect.
Do not use in arthritides of immunological origin (e.g. rheumatoid arthritis).

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:
Do not exceed the standard dose. Increasing the recommended dose may result in exacerbation of stiffness and discomfort.
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 has been reported that a dog which had suffered pulmonary lacerations twelve months previously had severe pulmonary bleeding after an injection of pentosan polysulphate sodium. Use with caution in dogs with a history of pulmonary lacerations.
Caution is also recommended in cases of hepatic impairment.
Pentosan polysulphate sodium has an anticoagulant effect.
It is recommended that the Packed Cell Volume (PVC) and capillary filling time should be monitored, when the veterinary medicinal product is used.
Avoid intramuscular injection because of the risk of haematoma at the injection site.
No more than three courses of four injections should be administered in a twelve month period.
It is recommended that the animal should be monitored for signs of blood loss and treated appropriately. Interrupt the treatment if signs of increased bleeding occur.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
The preservative, benzyl alcohol, can cause hypersensitivity (allergic) reactions in sensitised people. If you know that you are sensitised, care should be taken when handling this veterinary medicinal product. If accidental skin or eye contact occurs, rinse affected area immediately with water.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):	Injection site reaction[1]
Very rare (1 animal / 10 000 animals treated, including isolated reports):	Vomiting[2] Depression[3] and lethargy[4,6]
Undetermined frequency (cannot be estimated from the available data)	Prolonged activated partial thrombin time (APTT) and thrombin time (TT)[5] Emesis[6], diarrhoea[6], anorexia[6] Bleeding disorders (such as nasal bleeding, haemorrhagic diarrhoea and haematomas) Local reactions (e.g. swelling[7])

[1] May occur within 24 hours in an apparently healthy animal. Treatment should be discontinued and symptomatic relief given.
[2] Occurs immediately after injection. Such dogs generally require no medical treatment and make an uneventful recovery. Further treatment with pentosan polysulphate is not recommended.
[3] Apparently mild.
[4] Lasts up to 24 hours.
[5] 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 polysulphate 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.
[6] These signs may be the result of a hypersensitivity reaction and may require appropriate symptomatic treatment including antihistamine administration.
[7] 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 also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
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 veterinary medicinal product in the pregnant or lactating animal has not been studied, therefore use is not recommended in pregnant or lactating animals.
The veterinary medicinal 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 polysulphate sodium as they may affect thrombocyte adhesion and potentiate the anticoagulant activity of the veterinary medicinal 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 the veterinary medicinal product.

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.

3.9 Administration routes and dosage

Subcutaneous use.
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. An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.
To establish the appropriate dosage, the weight of the individual animal should be determined prior to administering the veterinary medicinal product.

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

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.
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

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QM01AX90.

4.2 Pharmacodynamics

The veterinary medicinal product contains Pentosan Polysulphate 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.
Pentosan polysulphate sodium 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.

4.3 Pharmacokinetics

Absorption: In the dog, a peak plasma concentration of 7.40 µg-eq pentosan polysulphate sodium/mL is achieved 15 minutes after subcutaneous administration.

Distribution: Pentosan polysulphate sodium binds many plasma proteins with a variable strength of association and dissociation resulting in a complex equilibrium between bound and unbound drug. Pentosan polysulphate sodium is concentrated in the liver and kidneys and reticuloendothelial system. Low levels occur in connective tissue and muscle The volume of distribution in dogs is 0.43 L.

Biotransformation: Desulfation of pentosan polysulphate 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 veterinary medicinal 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

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.
Shelf life after first opening the immediate packaging: 84 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Colourless glass vial fitted with a grey chlorobutyl stopper and sealed by a lacquered aluminium cap.
Package size:
1 x 10ml
1 x 20ml
Not all pack sizes may be marketed.

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 or household waste.

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

Chanelle Pharmaceuticals Manufacturing Limited

7. MARKETING AUTHORISATION NUMBER

Vm 08749/4086

8. DATE OF FIRST AUTHORISATION

19 July 2018

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

March 2025

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: 01 July 2025