IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Osteopen 100 mg/ml Solution for injection Dogs

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

PRODUCT SUMMARY

EU Procedure Number	IE/V/0382/001/DC
Name, Strength, Pharmaceutical Form	Osteopen 100mg/ml Solution for Injection for Dogs
Active Substances(s)	Pentosan polysulphate sodium
Applicant	Chanelle Pharmaceuticals Manufacturing Limited Loughrea Co. Galway Ireland
Date of Authorisation	20/07/2018
Legal Basis of Application	Generic application (Article 13(1) of Directive No 2001/82/EC)
Target Species	Dogs
Indication For Use	For the treatment of lameness and pain of degenerative joint disease/osteoarthritis (non-infectious arthrosis) in the skeletally mature dog.
ATC Code	QM01AX90
Concerned Member States	AT, BE, CZ, CY, DE, DK, FI, FR, HU, IS, IT, NL, NO, PL, ES, RO, SE, SI, SK & UK

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.

It has been shown that the product can be safely used in the target species;

The product is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The efficacy of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

The product contains 100 mg/ml pentosane polysulfate sodium and the excipients benzyl alcohol, disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate, sodium hydroxide, hydrochloric acid and water for injections. The container/closure system is 10 ml or 20 ml Ph. Eur. Type I colourless glass vials fitted with grey chlorobutyl stoppers and sealed with lacquered aluminium caps.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is pentosane polysulfate sodium, an established active substance. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification has been provided.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on Intermediate Products

Not applicable.

E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods has been provided.
Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substance has been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product has been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

The application is for a solution for injection containing pentosan polysulphate sodium as active substance, for use in dogs. This application is submitted by Chanelle Pharmaceuticals Manufacturing Limited. The legal basis for the application is in accordance with paragraph 1 of Article 13 of Directive 2001/82/EC, as amended (that is, a generic application). The reference veterinary medicinal product cited is Cartrophen Vet 100 mg/ml solution for injection containing 100 mg/ml pentosan polysulphate sodium as registered in Ireland (VPA 10890/001/001 – Arthropharm [Europe] Limited) since 1/10/1991. The product is intended for administration to dogs for the treatment of lameness and pain of degenerative joint disease/osteoarthiritis (non-infectious arthorisis) in the dog and is intended for subcutaneous administration at a dose rate of 3 mg pentosan polysulphate sodium per kg bodyweight on four occasions with an interval of 5-7 days.

The omission of *in-vivo* bioequivalence data was accepted based upon satisfactory demonstration of essential similarity between the generic and reference product formulations.

As this is a generic application according to paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with a reference product has been accepted, results of safety tests are not required.

The safety aspects of this product are considered to be the same as for the reference product.

Warnings and precautions as listed on the product literature are in line with those of the reference product and other similar products that have been recently authorised and are considered adequate to ensure safety of the product for users and the environment.

III.A Safety Testing

Pharmacological Studies

As this is an application for a generic product in accordance with paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with the reference product has been accepted, no pharmacological study data was required.

The pharmacokinetic and pharmacodynamic characteristics of the product are not expected to differ to those of the reference product.

Toxicological Studies

As this is an application for a generic product in accordance with paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with the reference product has been accepted, no toxicological study data was required. The toxicological profile of the product is not expected to differ to that of the reference product.

User Safety

A user safety assessment was provided. Based upon satisfactory demonstration of essential similarity between the generic and reference product formulations, it was accepted that no difference in terms of safety for the user is anticipated between generic and reference products. Further, the product is intended to be administered to the same target species, using the same route of administration at the same dose rate as already approved for the reference product.

Warnings and precautions as listed on the product literature are considered adequate to ensure safety to users of the product. It was concluded that the product will not present an unacceptable risk for the user when handled, used, stored and disposed of in accordance with the recommendations included in the SPC.

Environmental Risk Assessment

An environmental risk assessment
was provided ***Phase I***

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the product is only intended for administration to non-food producing animals.

It was concluded that the product will not present an unacceptable risk for the environment when handled, used, stored and disposed of in accordance with the recommendations included in the SPC.

III.B Residues Documentation

Not applicable as the product is only intended for use in non-food producing animals.

IV. CLINICAL ASSESSMENT

As this is a generic application according to paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with a reference product has been accepted, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

As this is an application for a generic product in accordance with paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with the reference product has been accepted, no target animal tolerance study data was required.

Tolerance in the target animal is not expected to differ between the generic and reference products. Suitable warnings have been included in the SPC to ensure the safe use of the product in the target species, particularly in respect of the potential for an anti-coagulant effect of pentosane polysulphate and the avoidance of use in skeletally immature dogs.

The product literature accurately reflects the type and incidence of adverse effects which might be expected following use of the product.

Field Trials

As this is an application for a generic product in accordance with paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with the reference product has been accepted, no field trials were required.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

VI. POST-AUTHORISATION

ASSESSMENTS None.