IPAR

Public Assessment Report for a
Medicinal Product for Human Use

Scientific Discussion

Sodium Chloride 0.9% w/v Injection BP
Sodium chloride
PA1122/002/001

The Public Assessment Report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of a marketing authorisation for a specific medicinal product for human use. It is made available by the HPRA for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of Directive 2001/83/EC, as amended. 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 medicinal product for marketing in Ireland.

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I. INTRODUCTION

This product was initially authorised under procedure number UK/H/0859/001/DC with the UK as RMS. The responsibility of RMS was transferred to Ireland on 08th October 2018 under procedure number IE/H/0699/001/DC.

Please note the following detail for the product in IE:
Marketing Authorisation Number: PA1122/002/001
Marketing Authorisation Holder: Noridem Enterprises Ltd.

The current Summary of Product Characteristics (SmPC) for this medicinal product is available on the HPRA website at www.hpra.ie.

The UK public assessment report published at the time of the initial marketing authorisation is provided herein.

Product Name	Sodium Chloride 0.9% w/v Injection BP
Type of Application	Known Active Substance Initial application Bibliographic (Article 10a) Chemical substance Prescription only
Active Substance	Sodium chloride
Form	Solvent for parenteral use, 0.9% w/v
MA Holder	Noridem Enterprises Ltd, Evagorou & Makariou, Mitsi Building 3, Suite 115, 1065 Nicosia, Cyprus
RMS	United Kingdom
CMS	Austria, Belgium, Denmark, Germany, Greece, Ireland, The Netherlands, Norway, Portugal, Spain, Sweden
Procedure Number	UK/H/0859/001/MR
Timetable	Day 90: 11/11/2007

Background
This application was submitted by Noridem Enterprises Limited for Sodium Chloride 0.9% w/v Injection BP, via the Mutual Recognition Procedure. The UK acted as Reference Member State for the procedure, which was granted a UK licence on 26th August 2004.

Sodium Chloride 0.9%w/v Injection is indicated as a pharmaceutical aid and diluent for the infusion of compatible drug additives and for diluting or dissolving drugs for parenteral administration.

Other indications for sodium chloride injection include flushing of IV catheters, as a priming solution in haemodialysis procedures and to initiate and terminate blood transfusions (without haemolysing red blood cells). Sodium chloride injection may be added to compatible carbohydrate solutions, such as dextrose in water, to produce electrolytes.

Based on the review of the data on quality, safety and efficacy, the RMS considered that the application for Sodium Chloride 0.9% w/v Injection BP could be approved for the indications stated above.

Day 90 for the procedure was 11th November 2007, subsequent to which Marketing Authorisations were approved in Austria, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Ireland, Latvia, Lithuania, Luxembourg, The Netherlands, Poland, Portugal, Slovak Republic, Spain and Sweden.

Overall Benefit/Risk Assessment
Sodium Chloride 0.9% w/v Injection BP is a well-known and widely used solvent. It is compatible with an extensive number of substances and can be used as a vehicle/diluent for the parenteral administration of other medicinal products.

No preclinical studies were conducted, and none are required as the product is well-established for medicinal use.

No clinical studies were conducted, and none are required as the product is well-established for medicinal use.

The RMS has been assured that acceptable standards of GMP are in place at all sites responsible for the manufacture and assembly of this product prior to granting its national authorisation.

For manufacturing sites within the community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

II. QUALITY ASPECTS

S. Active Substance

Synthesis of the drug substance from the designated starting materials has been adequately described, and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents, and these are supported by relevant certificates of analysis.

An appropriate specification is provided for the active substance sodium chloride, with suitable test methods and limits. Batch analysis data are provided and comply with the proposed specification.

The active sodium chloride is packaged in multiple layer paper bags. Suitable specifications have been provided for all packaging materials and the primary packaging has been shown to comply with current guidelines concerning contact with foodstuff.

Appropriate shelf-lives have been set for active sodium chloride, based on the available stability data provided by the active substance manufacturers. No formal stability data has been provided by the applicant, which is acceptable given that the active is known to be very stable and the European Pharmacopoeia monograph contains no degradation products.

P. Medicinal Product

Other Ingredients

The only excipient used in this product is water for injections. Satisfactory certificates of analysis have been provided to show that it complies with the current European Pharmacopoeia monograph.

No excipients of human or animal origin are used in this product. No genetically modified organisms are used in this product.

Pharmaceutical Development

The objective of the development programme was to produce a solution for injection containing 0.9% w/v sodium chloride that complied with the current British Pharmacopoeia monograph.

Manufacturing Process

An appropriate account of the manufacturing process has been provided. The manufacturing process has been validated and has shown satisfactory results.

Finished Product Specification

The finished product specification is satisfactory and in-line with the current British Pharmacopoeia monograph. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification. Certificates of analysis have been provided for any working standards used.

Container-Closure System

The product is packed into polypropylene 5 or 10ml ampoules packed into cartons of 50 or 20ml ampoules packed into cartons of 20.

Satisfactory specifications and certificates of analysis have been provided for all packaging components. All primary packaging complies with the relevant regulations regarding materials for parenteral use.

Product Stability

Stability studies were performed in the packaging proposed for marketing and in accordance with current guidelines. All results from stability studies were within specified limits. These data support a shelf-life of 2 years with the storage condition 'Store below 25°C'.

Bioequivalence/Bioavailability

No bioequivalence studies have been submitted for this application and none were required.

Summary of Product Characteristics (SPC), Patient Information Leaflet (PIL), Labels
The SPC, PIL and Labels are pharmaceutically acceptable.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC, as amended. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

MAA Forms
The MAA forms are pharmaceutically satisfactory.

Expert Report
The pharmaceutical expert report has been written by an appropriately qualified person and is a suitable summary of the pharmaceutical dossier.

Conclusion
The grant of a marketing authorisation is recommended.

III. NON-CLINICAL ASPECTS

No new preclinical data have been supplied with this application and none are required for an application of this type.

IV. CLINICAL ASPECTS

Clinical Pharmacology
No new data were submitted and none are required for this type of application.

Efficacy
No new data were submitted and none are required for this type of application.

Safety
No new data were submitted and none are required for this type of application.

Summary of Product Characteristics (SPC), Patient Information Leaflet (PIL), Labels
The SPC, PIL and labels are medically acceptable. The SPC is consistent with that for other similar products.

Conclusion
The grant of a marketing authorisation is recommended.

V. OVERALL CONCLUSIONS

Quality
The important quality characteristics of Sodium Chloride 0.9% w/v Injection BP are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

NON-CLINICAL
No new preclinical data were submitted and none were required for an application of this type.

EFFICACY
No significant new or unexpected safety concerns were found during the clinical development.

The SPC, PIL and labelling are appropriate for a product of this type.

BENEFIT-RISK ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. Extensive clinical experience with Sodium Chloride 0.9% w/v Injection BP is considered to have demonstrated the therapeutic value of the compound. The benefit-risk is considered to be positive.

VI. REVISION DATE

May 2021

VII. UPDATES

Scope	Procedure number	Product information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval
RMS Transfer	From UK/H/0859/001/DC to IE/H/0699/001/DC	N/A	N/A	N/A	Approved 08/10/2018