IPAR

Public Assessment Report for a
Medicinal Product for Human Use

Scientific Discussion

Water for Injections Ph Eur
Water for injections
PA1122/001/001

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.

CONTENTS

I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the HPRA has granted a marketing authorisation for Water for Injections Ph. Eur., from Noridem Enterprises Limited, on 14th November 2007. Water for Injections is used to dissolve or dilute some medicines so that they can be given as an injection or an infusion (a drip) into veins, muscles or other tissues in the body.

This product was initially authorised under procedure number UK/H/0878/001/DC with the UK as RMS and AT, BE, DE, DK, EL, ES, NL, NO, PT and SE as CMSs. The responsibility of RMS was transferred to Ireland on 08th October 2018 under procedure number IE/H/0698/001/DC.

In this repeat use procedure IE/H/0698/001/E/001 authorisation was further extended to CMS's CZ, FI, HU, IT, PL, RO and SK.

This medicine is subject to medical prescription.

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

Name of the product	Water for Injections Ph. Eur.
Name(s) of the active substance(s) (INN)	Water for Injections
Pharmacotherapeutic classification (ATC code)	V07AB
Pharmaceutical form and strength(s)	Solvent for parenteral use
Marketing Authorisation Number(s) in Ireland (PA)	PA1122/001/001
Marketing Authorisation Holder	Noridem Enterprises Limited
MRP/DCP No.	IE/H/0698/001/E/001
Reference Member State	IE
Concerned Member State	CZ, FI, HU, IT, PL, RO, SK

II. QUALITY ASPECTS

II.1. Introduction

This application is for Water for Injections Ph. Eur.

II.2 Drug substance

As the only constituent in this product is water for injections, no active substance data was submitted or required.

II.3 Medicinal product

P.1 Composition

The only constituent of this product is water for injections. No materials of human or animal origin are used in the production of water for injections. No genetically modified organisms are used in the production of water for injections.

P.2 Pharmaceutical Development

Water for Injections has been developed according to the corresponding European Pharmacopoeia monograph as a vehicle for dilution and reconstitution of suitable medicinal products for parenteral administration.

P.3 Manufacture of the Product

The product is manufactured in accordance with the principles of good manufacturing practice (GMP) at suitably qualified manufacturing sites.

The manufacturing process has been validated according to relevant European/ICH guidelines and the process is considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients/*Ancillary Substances*)

The only ingredient is water for injections.

P.5 Control of Finished Product

The finished product specification is satisfactory and in-line with the current European Pharmacopoeia for water for injections. 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.

P.6 Packaging material
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.

P.7 Stability of the Finished Product
Stability data on the finished product in the proposed packaging have been provided in accordance with EU guidelines and support the shelf-life and storage conditions listed in sections 6.3 and 6.4 of the SmPC.

II.4 Discussion on Chemical, Pharmaceutical and Biological Aspects

The important quality characteristics of the product are well-defined and controlled. Satisfactory chemical and pharmaceutical documentation has been provided, assuring consistent quality of Water for injections.

III. NON-CLINICAL ASPECTS

III.1 Introduction
No new preclinical data have been supplied with this application and none are required for an application of this type.

III.2 Pharmacology
No new data were submitted and none are required for this type of application.

III.3 Pharmacokinetics
No new data were submitted and none are required for this type of application.

III.4 Toxicology
No new data were submitted and none are required for this type of application.

III.5 Ecotoxicity/environmental risk assessment
No new data were submitted and none are required for this type of application.

III.6 Discussion on the non-clinical aspects
The granting of a Marketing Authorisation is recommended.

IV. CLINICAL ASPECTS

IV.1 Introduction
No new data were submitted and none are required for this type of application.

IV.2 Pharmacokinetics
No new data were submitted and none are required for this type of application.

IV.3 Pharmacodynamics
No new data were submitted and none are required for this type of application.

IV.4 Clinical Efficacy
No new data were submitted and none are required for this type of application.

IV.5 Clinical Safety
No new data were submitted and none are required for this type of application.

IV.6 Discussion on the clinical aspects

The granting of a Marketing Authorisation is recommended.

V. OVERALL CONCLUSIONS

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. Extensive clinical experience with Water for Injections is considered to have demonstrated the therapeutic value of the compound. The benefit-risk is considered to be positive.