IPAR

Public Assessment Report for a
Medicinal Product for Human Use

Scientific Discussion

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

An Irish national marketing authorisation was granted on 21st October 2005 to Neolab Ltd,; on the basis of Directive 2001/83/EC Article 10.1 (a) (iii) demonstrating essential similarity with Telfast® tablets.
for Fexofast 120 mg and 180 mg tablets.
The approved therapeutic indications are *"Relief of symptoms associated with seasonal allergic rhinitis"*for the 120 mg tablets and '*Relief of symptoms associated with chronic idiopathic urticaria*' for the 180 mg tablets.

II. QUALITY ASPECTS

Introduction

The product is a film-coated tablet, containing either 120 mg or 180 mg of fexofenadine hydrochloride, equivalent to 112 mg or 168 mg of fexofenadine.
All manufacturing operations are conducted in accordance with Good Manufacturing Practice. The manufacturer is Fannin (UK) Ltd., Wellingborough, Northamptonshire, United Kingdom; this site holds a valid manufacturing licence issued by the UK competent authority.

Drug Substance

Fexofenadine hydrochloride is an established active substance described in the European Pharmacopoeia (Ph. Eur.), which is manufactured in accordance with Good Manufacturing Practice (GMP).
The active substance specification is considered adequate to control the quality and meets the current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification have been provided.

Medicinal Product

Composition
Fexofast tablets contain the active substance fexofenadine hydrochloride and the following other ingredients; microcrystalline cellulose, maize starch, magnesium stearate, croscarmellose sodium and povidone. The tablet coating is composed of hypromellose, macrogol, titanium dioxide (E171) and iron oxide (E172). All excipients are commonly used in pharmaceutical products.

Container / Closure System
The product is presented as a blister pack of PVC/PVdC/aluminium foil in an outer cardboard carton.

Pharmaceutical Development
The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.
The applicant demonstrated that the product is a stable product that is essentially similar to the reference product, 'Telfast' 120 mg and 180 mg tablets, marketed in Ireland.

Manufacture of the Product
The product is manufactured in accordance with conventional manufacturing techniques for this product type (film-coated tablet). The product is manufactured in compliance with the principles of Good Manufacturing Practice and the manufacturing process has been validated according to relevant European / ICH guidelines.
Product Specifications
The finished product specification is based on the Ph. Eur. monograph for tablets with some additional tests specific for this product.
Batch analytical data has been provided demonstrating compliance with the specification and thus showing the ability of the manufacture to produce finished product of consistent quality.

Product Stability
Stability data on the finished product in the proposed packaging have been provided in accordance with EU guidelines demonstrating the stability of the product for three years with no special precautions for storage.

Information provided on chemical and pharmaceutical aspects of the product is considered sufficient and meets current regulatory requirements. There are no ingredients of biological origin in the product.

III. NON-CLINICAL ASPECTS

Introduction

The pharmacodynamic, pharmacokinetic and toxicological properties of fexofenadine are well known. As fexofenadine is a widely used, well-known active substance, the applicant has not provided additional studies and further studies are not required. An overview based on literature review is, thus, appropriate.

IV. CLINICAL ASPECTS

Introduction

The application is supported by an open bioequivalence study comparing the test and reference (Telfast) products which was conducted at GVK Biosciencees Ltd. Hyderabad, India, from January to February 2005. The study is stated to have been carried out in concordance with the ICH guidance on Good Clinical Practice.

Pharmacokinetics

The principal pharmacokinetic parameters of the test and reference products are shown in Table 1 intra-individual coefficient of variation was similar between the test and reference products.

Table 1 Pharmacokinetics indices for test and reference brands of fexofenadine.

AUC (0-inf)
g.hr/ml
Cmax (ng/mL)
Tmax (h)

Test	Reference	Mean*ratio t/r (90%CI)
4722 ± 2590	4806 ± 2903	97.9 (87.3 – 109.8)
706 ± 447	736 ± 475	96.6 (86.9 – 107.4)
2.8 ± 1.4	2.8 ± 1.6	NA

*logtransformed geometric mean

Clinical safety
The Marketing Authorisation Holder submitted a set of documents describing the Pharmacovigilance System, including information on the availability of an EU Qualified Person for Pharmacovigilance (EU-QPPV) and the means for notification of adverse reaction reports in the EU or from a Third Country.
Discussion on the clinical aspects

Neolabs Ltd has demonstrated that these generic Fexofast 120 mg and 180 mg Film-coated Tablets are bioequivalent with the innovator product Telfast. The product information (SPC and PIL) is appropriate.

V. OVERALL CONCLUSIONS

The Neolab generic product is bioequivalent to the innovator product and the product information is the same as that approved for the innovator, the risk benefit of the generic product is therefore considered to be positive.

VI. REVISION DATE

June 2021

VII. UPDATES

The name of the medicinal product was updated in IE only from Fexofenadine 120 mg film-coated tablets and Fexofenadine 180 mg film-coated tablets to Fexofast 120 mg film-coated tablets and Fexofast 180 mg film-coated tablets, via procedure IE/H/230/01-02/1B/004, on 22/02/2013.

SCOPE	PROCEDURE NUMBER	PRODUCT INFORMATION AFFECTED	DATE OF START OF PROCEDURE	DATE OF END OF PROCEDURE
MA transfer	CRN00CF0P	SmPC section 7, 8, 10 Package Leaflet New MA Holder: Cipla Europe NV New PA number: PA1963/014/002	N/A	18/06/2021