Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Fexofenadine hydrochloride 120 mg film-coated tablets
Fexofenadine hydrochloride 180 mg film-coated tablets

fexofenadine hydrochloride

PL 17780/1108-1109

Zentiva Pharma UK Limited

LAY SUMMARY

Fexofenadine hydrochloride 120 mg and 180 mg film-coated tablets
fexofenadine hydrochloride

This is a summary of the Public Assessment Report (PAR) for Fexofenadine hydrochloride 120 mg and 180 mg film-coated tablets. It explains how these products were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

These products will be referred to as Fexofenadine hydrochloride film-coated tablets in this lay summary for ease of reading.

For practical information about using Fexofenadine hydrochloride film-coated tablets, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What are Fexofenadine hydrochloride film-coated tablets and what are they used for?
These applications are the same as Telfast 120 mg and 180 mg film-coated tablets (PL 53886/0062 and PL 53886/0063) which are already authorised.

The Company responsible for Telfast 120 mg and 180 mg film-coated tablets has agreed that its scientific data can be used as the basis for the grant of identical licences for Fexofenadine hydrochloride film-coated tablets.

Fexofenadine hydrochloride 120 mg film-coated tablets are used in adults and adolescents of 12 years and older to relieve the symptoms that occur with hay fever (seasonal allergic rhinitis) such as sneezing, itchy, runny or blocked nose and itchy, red and watery eyes.

Fexofenadine hydrochloride 180 mg film-coated tablets are used in adults and adolescents of 12 years and older to relieve the symptoms that occur with long term allergic skin reactions (chronic idiopathic urticaria) such as itching, swelling and rashes.

How do Fexofenadine hydrochloride film-coated tablets work?
Fexofenadine hydrochloride film-coated tablets contain the active substance fexofenadine hydrochloride, which is a non-drowsy antihistamine.

How are Fexofenadine hydrochloride film-coated tablets used?
The pharmaceutical form of these medicines is a film-coated tablet and the route of administration is oral (taken by mouth).

Fexofenadine hydrochloride 120 mg film-coated tablets
For adults and children aged 12 years and over: The recommended dose is one tablet (120 mg) daily. The patient should take their tablet with water before a meal. This medicine starts to relieve the patient's symptoms within 1 hour and lasts for 24 hours.

Fexofenadine hydrochloride 180 mg film-coated tablets
For adults and children aged 12 years and over: The recommended dose is one tablet (180 mg) daily. The patient should take their tablet with water before a meal. This medicine starts to relieve the patient's symptoms within 1 hour and lasts for 24 hours.

For further information on how Fexofenadine hydrochloride film-coated tablets are used, refer to the PIL and Summaries of Product Characteristics (SmPCs) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

These medicines can only be obtained with a prescription.

The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

What benefits of Fexofenadine hydrochloride film-coated tablets have been shown in studies?
Fexofenadine hydrochloride film-coated tablets are considered identical to the previously authorised products with the same benefits and risks. No new studies have been provided for Fexofenadine hydrochloride film-coated tablets, however, reference is made to the studies for Telfast 120 mg and 180 mg film-coated tablets.

What are the possible side effects of Fexofenadine hydrochloride film-coated tablets?
For the full list of all side effects reported with these medicines, see Section 4 of the PIL or the SmPCs available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.ukor search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Fexofenadine hydrochloride film-coated tablets are considered to be identical to the previously authorised products with the same benefits and risks.

Why were Fexofenadine hydrochloride film-coated tablets approved?
The MHRA decided that the benefits of Fexofenadine hydrochloride film-coated tablets are greater than the risks and recommended that these medicines are approved for use.

What measures are being taken to ensure the safe and effective use of Fexofenadine hydrochloride film-coated tablets?
As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Fexofenadine hydrochloride film-coated tablets The RMP details the important risks of Fexofenadine hydrochloride film-coated tablets, how these risks can be minimised, any uncertainties about Fexofenadine hydrochloride film-coated tablets (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Fexofenadine hydrochloride film-coated tablets:

Summary of safety concerns	
Important identified risks	• Systemic hypersensitivity reactions
Important potential risks	• Cardiovascular events (i.e. tachycardia and palpitations)
Important missing information	• Use in pregnant and lactating women

Summary of safety concerns	
	• Treatment of SAR in children aged less than 6 years old for fexofenadine 30mg • Treatment of CIU in children aged less than 12 years old for fexofenadine 180mg

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Fexofenadine hydrochloride film-coated tablets are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

Other information about Fexofenadine hydrochloride film-coated tablets
Marketing Authorisations were granted in the United Kingdom on 21 February 2023.

The full PAR for Fexofenadine hydrochloride film-coated tablets follows this summary.
This summary was last updated in March 2023.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the applications for Fexofenadine hydrochloride 120 mg and 180 mg film-coated tablets (PL 17780/1108-1109) could be approved.

The products are approved for the following indications:

- Fexofenadine hydrochloride 120 mg is indicated in adults and children 12 years and older for the relief of symptoms associated with seasonal allergic rhinitis.

- Fexofenadine hydrochloride 180 mg is indicated in adults and children 12 years and older for the relief of symptoms associated with chronic idiopathic urticaria.

Fexofenadine hydrochloride, the active substance, is a non-sedating H_1 antihistamine. Fexofenadine is a pharmacologically active metabolite of terfenadine.

These are national applications approved under Regulation 56 of The Human Medicines Regulation 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended) as informed consent applications. The applications cross-refer to the reference products Telfast 120 mg and 180 mg film-coated tablets (PL 53886/0062 and PL 53886/0063).

No new non-clinical or clinical data have been supplied and none are required for these informed consent applications.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment (ERA). As the applications are for identical versions of already authorised products, no increase in environmental exposure is anticipated and no ERA is required.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for these products at all sites responsible for the manufacture, assembly and batch release of these products.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

National marketing authorisations were granted in the United Kingdom on 21 February 2023

II. EXPERT REPORT

The applicant cross-refers to the data for Telfast 120 mg and 180 mg film-coated tablets (PL 53886/0062 and PL 53886/0063; Opella Healthcare UK Limited), to which these applications are claimed to be identical. This is acceptable.

III. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION

Summaries of Product Characteristics (SmPCs)

The SmPCs are in line with those for Telfast 120 mg and 180 mg film-coated tablets, dated 11/2021.

PATIENT INFORMATION LEAFLET
A mock-up has been provided which has been aligned with that for Telfast 120 mg and 180 mg film-coated tablets, dated for 06/2021. The user test report submitted for PL 53886/0062 has been provided, along with a bridging report for the 180 mg strength.

LABEL
Label mock-ups have been provided.

IV. QUALITY ASPECTS

IV.1 Drug Substance

Drug substance specifications
The source of the active substance is in line with the cross-reference products. The proposed drug substance specification is consistent with the details registered for the cross-reference products.

IV.2. Drug Product

Name
The product has been named in line with current requirements.

Strength, pharmaceutical form, route of administration, container and pack sizes
Fexofenadine hydrochloride film-coated tablets are available in PVC/PE/PVDC/Al or PVC/PVDC/Al blisters, packaged into cardboard boxes.

Pack sizes:
120 mg: 7, 10, 15, 20, 30, 50, 100 and 200 tablets per package.
180 mg: 10, 15, 20, 30, 50, 100 and 200 tablets per package.

Not all packs sizes may be marketed

The appearance of the products is identical to that of the cross-reference products.

The proposed shelf life of the product is 3 years with no special storage conditions.

The proposed packaging, shelf life and storage conditions are consistent with the details registered for the reference product.

Legal status
Prescription only medicine (POM).

Manufacturers
The proposed manufacturing sites are consistent with the details registered for the cross-reference products and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

Qualitative and quantitative compositions
The composition of the proposed products is consistent with the details registered for the cross-reference products.

Manufacturing process & control of critical steps
The proposed manufacturing processes and process controls are consistent with the details registered for the reference products and the maximum batch size is stated.

Finished product release/shelf life specifications
The finished product specifications at release and shelf-life are in line with the details registered for the cross-reference products.

TSE Compliance
No excipients of animal or human origin are used in the final products.

Confirmation has been given that the magnesium stearate used in the tablets is of vegetable origin.

These products do not contain or consist of genetically modified organisms (GMO).

V. NON-CLINICAL ASPECTS
As these applications are submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as informed consent applications) no new non-clinical data have been supplied and none are required.

VI. CLINICAL ASPECTS
As these applications are submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as informed consent applications) no new clinical data have been supplied and none are required.

VII. RISK MANAGEMENT PLAN (RMP)
The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

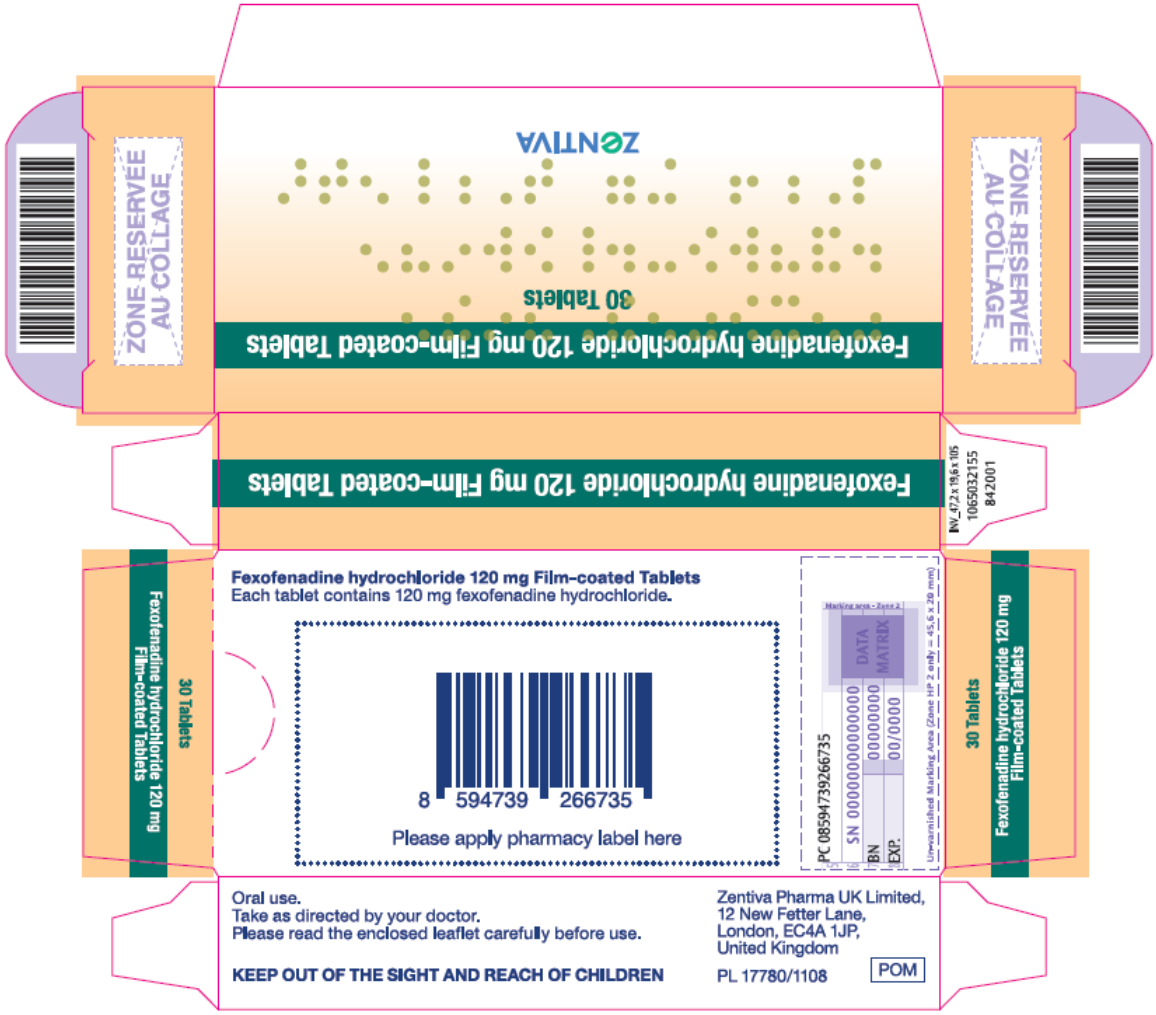
VIII. USER CONSULTATION
A full colour mock-up of the Patient Information Leaflet (PIL) has been provided with the application, in accordance with legal requirements.

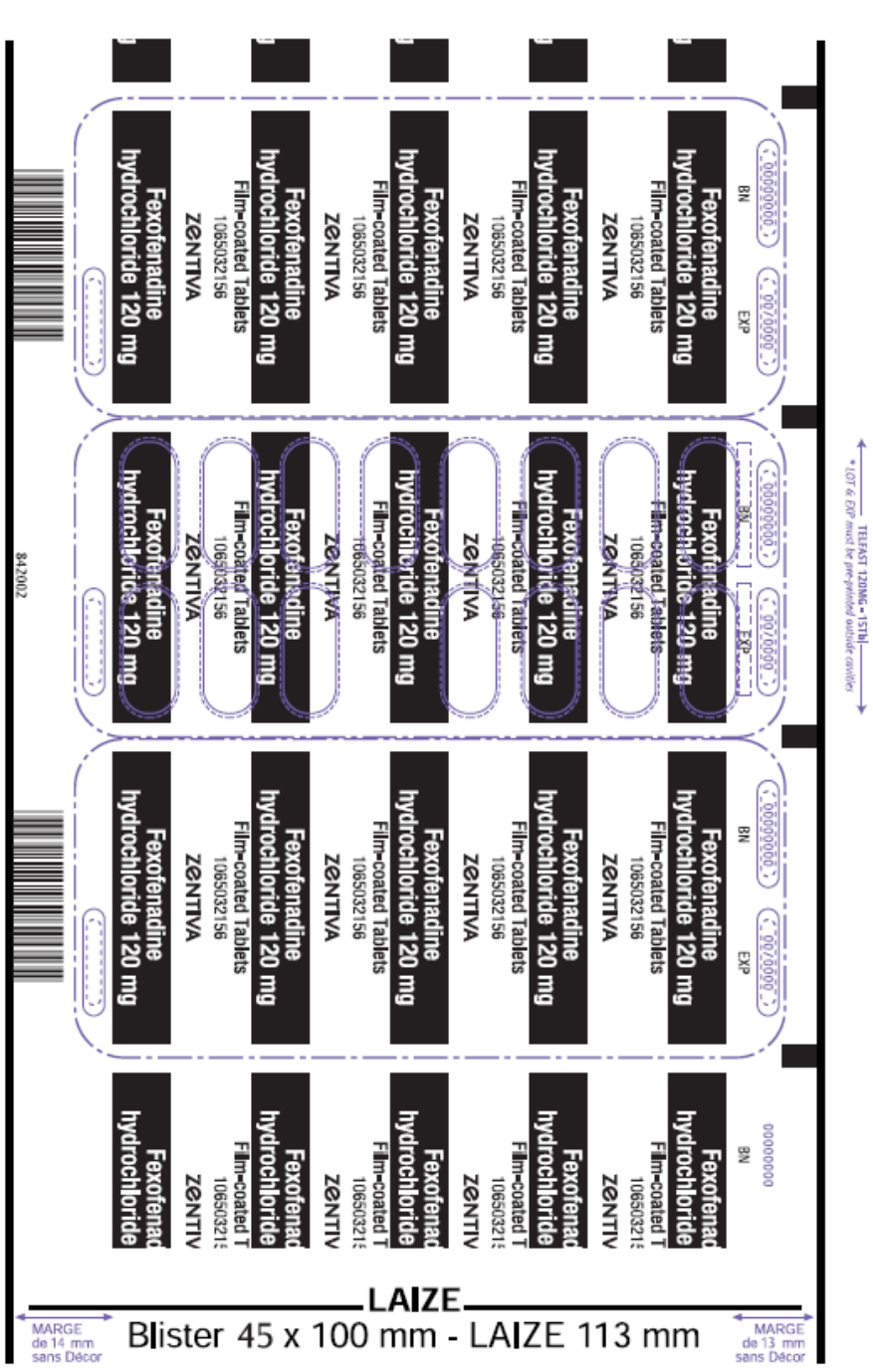
The PIL has been evaluated via a user consultation with target patient groups, in accordance with legal requirements, on the basis of a bridging report making reference to Telfast 120 mg film-coated tablets and Telfast 180 mg film-coated tablets (PL 53886/0062 and PL 53886/0063, Opella Healthcare UK Limited). The bridging report submitted by the applicant is acceptable.

IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant's products are identical to the cross-reference products. The benefit/risk balance is, therefore, considered to be the same as for the cross-reference products and positive.

The Summaries of Product Characteristics (SmPCs), Patient Information Leaflets (PILs) and labelling are satisfactory, in line with current guidelines and consistent with the cross-reference products.
In accordance with legal requirements, the current approved UK versions of the SmPCs and PILs for these products are available on the MHRA website.

Representative copies of the labels at the time of licensing are provided below.




LAIZE
Blister 45 x 100 mm - LAIZE 113 mm
MARGE de 14 mm sans Décor
MARGE de 13 mm sans Décor
Fexofenadine hydrochloride 120 mg
Film-coated Tablets
ZENTIVA
BN
EXP
842002

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Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations where significant changes are made are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPC and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**