Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Furonex 27.5 micrograms per spray, nasal spray suspension

fluticasone furoate

PLGB 56740/0001

Abdi Farma GmbH

LAY SUMMARY

Furonex 27.5 micrograms per spray, nasal spray suspension
fluticasone furoate

This is a summary of the Public Assessment Report (PAR) for Furonex 27.5 micrograms per spray, nasal spray suspension. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product will be referred to as Furonex in this lay summary for ease of reading.

For practical information about using Furonex, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Furonex and what is it used for?
This application is for a hybrid medicine. This means that the medicine is similar to a reference medicine already authorised, called AVAMYS 27.5 micrograms/spray, nasal spray suspension. The application is for a hybrid medicine because the products are locally acting.

Furonex nasal spray contains the active substance fluticasone furoate. Furonex nasal spray is used to treat symptoms of allergic rhinitis including stuffy, runny or itchy nose, sneezing and watery, itchy or red eyes, in adults and children aged 6 years and over.

How does Furonex work?
Furonex belongs to a group of medicines called *glucocorticoids*. Furonex works to decrease inflammation caused by allergy (*rhinitis*) and therefore reduce symptoms of allergy.

Allergy symptoms can occur at specific times of the year and be caused by allergy to pollen from grass or trees (hayfever), or they can occur all year round and be caused by allergy to animals, house-dust mites or moulds to name some of the most common.

How is Furonex used?
The pharmaceutical form of this medicine is nasal spray, suspension and the route of administration is nasal use (sprayed into the nose).

Due to the high-level of detail in the usage instructions it is best to refer directly to the PIL and Summary of Product Characteristics (SmPCs) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website, for information on how Furonex is used.

This medicine can only be obtained with a prescription.

The patient should always take this 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 Furonex have been shown in studies?
No additional studies were needed as Furonex contains the same active substance as the reference medicine, and satisfactory data to justify the differences have been provided.

What are the possible side effects of Furonex?
For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC 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.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Because Furonex is a hybrid medicine and is therapeutically equivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

Why was Furonex approved?
It was concluded that Furonex has been shown to be comparableto the reference medicine. Therefore, the MHRA decided that, as for the reference medicine, the benefits are greater than the risks and recommended that it can be approved for use.

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

The following safety concerns have been recognised for Furonex:

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 Furonex 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 this application and are satisfactory.

Other information about Furonex
A marketing authorisation for Furonex was granted in the Great Britain on 13 November 2024.

The full PAR for Furonex follows this summary.

This summary was last updated in January 2025.

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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 application for Furonex 27.5 micrograms per spray, nasal spray suspension (PLGB 56740/0001) could be approved.

The product is approved in adults, adolescents and children (6 years and over) for the following indication:
For the treatment of the symptoms of allergic rhinitis.

Mechanism of action
Fluticasone furoate is a synthetic trifluorinated corticosteroid that possesses a very high affinity for the glucocorticoid receptor and has a potent anti-inflammatory action.

This application was approved under Regulation 52A of The Human Medicines Regulation 2012, as amended (previously Article 10(3) of Directive 2001/83/EC, as amended), claiming to be a hybrid medicinal product of a suitable originator product, AVAMYS 27.5 micrograms/spray, nasal spray suspension that has been licensed for a suitable time, in line with the legal requirements.

No new non-clinical studies were conducted, which is acceptable given that the application is for a hybrid medicinal product of a suitable reference product.

A biowaiver was submitted with this application which was accepted. No bioequivalence or therapeutic equivalence studies were required and none were provided with this application.

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

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

A national marketing authorisation was granted in Great Britain on 13 November 2024.

II QUALITY ASPECTS

II.1 Introduction

What Furonex contains

The active substance is Fluticasone Furoate. It contains 0.55 mg Fluticasone Furoate per 1 ml. The other ingredients are glucose, microcrystalline cellulose and carmellose sodium, polysorbate 80, benzalkonium chloride, disodium edetate, and purified water.

The contents of the pack

Furonex is available in amber glass bottles fitted with a metered dose spray pump. Each bottle contains 120 sprays.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging complies with the current regulations concerning materials in contact with food.

II.2 ACTIVE SUBSTANCE

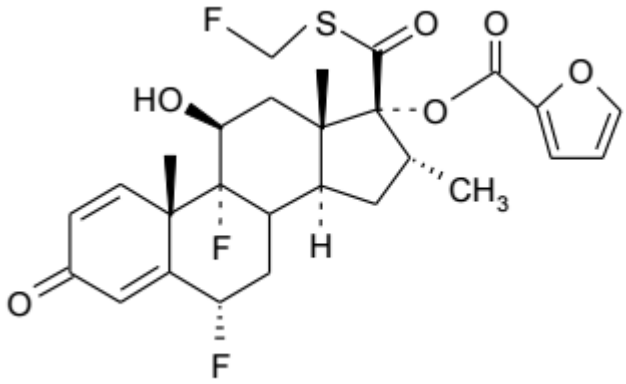
rINN: fluticasone furoate

Chemical Name: (6α,11β,-16α,17α)-6,9-Difluoro-17-{[(fluoro-methyl)thio]}-11-hydroxy-16-methyl-3-oxoandrosta-1,4-diene-17-yl2-Furancarboxylate

6S,9R,10S,11S,13S,14S,16R,17R)-6,9-difluoro-17-(((fluoromethyl)thio)carbonyl)-11-hydroxy-10,13,16-trimethyl-3-oxo-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-3H-cyclopenta[a]phenanthren-17-yl furan-2-carboxylate

Molecular Formula: $C_{27}H_{29}F_3O_6S$

Chemical Structure:



Molecular Weight: 538.58 g/mol

Appearance: White or almost white powder

Solubility:

Solubility

Solvent name	Parts of solvent required for 1 part of solute	Description term
Acetone	200	Slightly soluble
Methanol	179	Slightly soluble
Tetrahydrofuran	180	Slightly soluble
Methylene Chloride	88	Sparingly Soluble
Ethyl Acetate	40	Sparingly Soluble
N,N- Dimethyl formamide	45	Sparingly Soluble
Acetic Acid	570	Slightly Soluble
Water	10000	Insoluble
Acetonitrile	25	Soluble
Dimethyl sulphoxide	30	Soluble
Ethanol	240	Slightly Soluble
0.1 M NaOH	10000	Insoluble

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

Appropriate proof-of-structure data have been supplied for the active substance. All potential known impurities have been identified and characterised.

An appropriate specification is provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications. Batch analysis data are provided and comply with the proposed specification. Satisfactory Certificates of Analysis have been provided for all working standards.

Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current regulations concerning materials in contact with food.

Appropriate stability data have been generated supporting a suitable retest period when stored in the proposed packaging.

II.3 DRUG PRODUCT

Pharmaceutical development

A satisfactory account of the pharmaceutical development has been provided.

Comparative *in vitro* impurity profiles have been provided for the proposed and reference products.

All excipients comply with either their respective European/national monographs, or a suitable in-house specification. Satisfactory Certificates of Analysis have been provided for all excipients.

No excipients of animal or human origin are used in the finished product.

This product does not contain or consist of genetically modified organisms (GMO).

Manufacture of the product

A description and flow-chart of the manufacturing method has been provided.

Satisfactory batch formulation data have been provided for the manufacture of the product, along with an appropriate account of the manufacturing process. The manufacturing process has been validated and has shown satisfactory results.

Finished Product Specifications
The finished product specifications at release and shelf-life are satisfactory. The test methods have been described and adequately validated. Batch data have been provided that comply with the release specifications. Certificates of Analysis have been provided for any working standards used.

Stability
Finished product stability studies have been conducted in accordance with current guidelines, using batches of the finished product stored in the packaging proposed for marketing. Based on the results, a shelf-life of 24 months with the storage conditions 'Do not store above 25°C. Do not refrigerate or freeze. Store upright. Always keep the cap on' is acceptable. This product has an in-use shelf life of 2 months

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

II.4 Discussion on chemical, pharmaceutical and biological aspects
The grant of a marketing authorisation is recommended.

III NON-CLINICAL ASPECTS

III.1 Introduction
As the pharmacodynamic, pharmacokinetic and toxicological properties of fluticasone furoate is well-known, no new non-clinical studies are required, and none have been provided. An overview based on the literature review is, thus, appropriate.

III.2 Pharmacology
No new pharmacology data were provided and none were required for this application.

III.3 Pharmacokinetics
No new pharmacokinetic data were provided and none were required for this application.

III.4 Toxicology
No new toxicology data were provided and none were required for this application.

III.5 Ecotoxicity/Environmental Risk Assessment
Suitable justification has been provided for non-submission of an Environmental Risk Assessment. As this is/these are hybrid application of an already authorised product, it is not expected that environmental exposure will increase following approval of the Marketing Authorisation for the proposed product.

III.6 Discussion on the non-clinical aspects
The grant of a marketing authorisation is recommended.

IV CLINICAL ASPECTS

IV.1 Introduction

In accordance with the regulatory requirements, the applicant has provided a suitable biowaiver. Equivalence of the proposed drug product with the reference product was demonstrated through in vitro tests and as such no bioequivalence or therapeutic equivalence studies have been submitted with this application.

IV. 2 Pharmacokinetics

No new pharmacokinetic data have been submitted for this application and none were required.

IV.3 Pharmacodynamics

No new pharmacodynamic data have been submitted for this application and none were required.

IV.4 Clinical efficacy

No new efficacy data have been submitted for this application and none were required.

IV.5 Clinical safety

No new safety data were submitted with this application and none were required. The safety profile for this product is considered to be the same as AVAMYS 27.5 micrograms/spray, nasal spray suspension.

IV.6 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.

IV.7 Discussion on the clinical aspects

The grant of a marketing authorisation is recommended for this application.

V USER CONSULTATION

A grey-scale mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

VI OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified.

Extensive clinical experience with fluticasone furoate is considered to have demonstrated the therapeutic value of the product.

The benefit/risk is, therefore, considered to be positive.

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory and in line with current guidelines.

In accordance with legal requirements, the current approved versions of the SmPC and PIL for this product are available on the MHRA website.

TABLE OF CONTENT OF THE PAR UPDATE

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**