

Public Assessment Report Scientific discussion

Fluorette® Novum (Sodium fluoride)

Asp. no: 2006-0142

This module reflects the scientific discussion for the approval of Fluorette®Novum>. The procedure was finalised at 2008-01-25. For information on changes after this date please refer to the module 'Update'.

I. INTRODUCTION

Fertin Pharma A/S has applied for a marketing authorisation for Fluorette® Novum, medicated chewing-gum 0.25 mg. The active substance sodium fluoride is the same as in Fluorette® medicated chewing-gum, marketed by Fertin Pharma A/S since 1992. For approved indications, see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Fluorette Novum is presented in the form of medicated chewing-gum containing 0.550 mg of sodium fluoride which corresponds to 0.25 mg of fluoride. The excipients are acesulfame potassium, aspartame, chewing-gum base, maltitol, liquid maltitol, peppermint flavour, sorbitol, talc, xylitol, titanium dioxide, carnauba wax, gelatin and levomenthol. The medicated chewing-gums are packed in duplex blisters or in paperboard capsules

II.2 Drug Substance

Sodium fluoride has a monograph in the Ph Eur.

Sodium fluoride is a white or almost white powder or colourless crystals which is soluble in water. The structure of sodium fluoride has been adequately proven and its physico-chemical properties sufficiently described. The route of synthesis has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The active substance specification includes relevant tests and the limits for impurities/degradation products have been justified. The analytical methods applied are suitably described and validated.

Stability studies under ICH conditions have been conducted and the data provided are sufficient to confirm the retest period.

II.3 Medicinal Product

Fluorette® Novum medicated chewing-gum is formulated using excipients described in the current Ph Eur, except for the chewing-gum base and the peppermint aromas which are controlled according to acceptable in house specifications. All raw materials used in the product are of vegetable origin or has demonstrated compliance with Commission Directive 2003/63/EC and the NfG on Minimising the risk of transmitting Animal Spongiform Encephalopathy Agents via human and veterinary medicinal products (EMEA/410/01).

The product development has taken into consideration the physico-chemical characteristics of the active substance.

The manufacturing process has been sufficiently described and critical steps identified. Results from the process validation studies confirm that the process is under control and ensure both batch to batch reproducibility and compliance with the product specification.

The tests and limits in the specification are considered appropriate to control the quality of the finished product in relation to its intended purpose.

Stability studies under ICH conditions have been performed and data presented support the shelf life claimed in the SPC, when stored below 25°C.

III. NON-CLINICAL ASPECTS

There are no new non-clinical data that alters the risk/benefit assessment for this product compared with the original product.

IV. CLINICAL ASPECTS

IV.1 Clinical efficacy

Fluorette Novum consists of the same amount of active substance, 0.25 mg fluoride, as in the previously approved products Fluorette and Fluorette Cherry-Mint. The clinical efficacy of these products is previously demonstrated. Thus, no additional efficacy data was required.

IV.2 Clinical safety

Fluorette Novum consists of the same amount of active substance, 0.25 mg fluor, as in the previously approved products Fluorette and Fluorette Cherry-Mint. The clinical safety of these products is well known, when used according to the recommended dosage regimens. No specific safety concerns are anticipated for the new and the amended amounts of excipients. Thus, no additional safety data was required.

V. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

User testing of the package leaflet has not been performed as the application for market authorisation came to the MPA before the new legislation started.

The risk/benefit ratio is considered positive and Fluorette® Novum 0.25 mg medicated chewing-gum is recommended for approval.

VI. APPROVAL

Fluorette® Novum 0.25 mg medicated chewing-gum was approved in the national procedure on 2008-01-25

Public Assessment Report – Update

Scope	Procedure number	Product Information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval	Assessment report attached
						Y/N (version)