LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Lueva
(Desogestrel)

SE/H/1135/01/DC

This module reflects the scientific discussion for the approval of Lueva. The procedure was finalised at 2012-01-31. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

N.V. Organon has applied for a marketing authorisation for Lueva, 75 microgram, film-coated tablet. Lueva has the same composition and the same pharmaceutical form as Cerazette, 75 microgram, film-coated tablet, approved in Sweden on 1997-12-12, with N.V. Organon as marketing authorisation holder (identical to the proposed MAH for Lueva). The product contains desogestrel as active substance. For approved indications see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Lueva is presented in the form of film-coated tablets containing 75 micrograms of desogestrel. The excipients are colloidal anhydrous silica, all-rac-α-tocopherol, lactose monohydrate, maize starch, povidone, stearic acid, hypromellose, macrogol 400, talc and titanium dioxide (E 171). The tablets are packed in PVC/aluminium blister. Each blister contains 28 tablets. The days of the week are printed on the foil. Each carton contains 1, 3 or 6 blisters packed separately in an aluminium laminated sachet.

II.2 Drug Substance

Desogestrel has a monograph in the Ph Eur.

Desogestrel is a white or almost white, crystalline powder which is practically insoluble in water. The structure of desogestrel 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

Lueva, 75 microgram, film-coated tablet is formulated using excipients described in the current Ph Eur. 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, with no special storage precautions.

III. NON-CLINICAL ASPECTS

III.1 Discussion on the non-clinical aspects

The pharmacology, pharmacokinetics and toxicology of desogestrel are considered well known.

Environmental Risk Assessment
For desogestrel, a Phase I Environmental Risk Assessment investigation has been completed. The predicted environmental concentration (PECsurface water) for desogestrel is 0.0004 μg/L, which is below the regulatory action limit of 0.01 μg/L. Desogestrel and its biologically active metabolite etonogestrel are hormones and are regarded endocrine disrupters. Based on the conclusions of the Phase I investigation, a Phase II Tier A and Tier B investigation is currently ongoing and should be submitted when available (see Follow-up measures).

IV. CLINICAL ASPECTS

IV.1 Discussion on the clinical aspects

The human pharmacokinetics, pharmacodynamics, clinical efficacy and safety of desogestrel are considered well known as the clinical experience with the active compound is extensive.

Since this product has been shown to be essentially similar and refer to a product approved based on a full application with regard to clinical efficacy/safety data, no further such data have been submitted or are considered necessary.

V. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

User consultation

A user consultation with target patient groups on the package information leaflet (PIL) has been performed on the basis of the identity with the PIL for the product Cerazette, which was assessed and accepted in procedure SE/H/10147II/11.

The risk/benefit ratio is considered positive and Lueva, 75 microgram, film-coated tablet, is recommended for approval.

Follow-up measures:
Non-clinical

- ERA: The Phase II report should be submitted when available.

VI. APPROVAL

The Decentralised procedure for Lueva, 75 microgram, film-coated tablet, was successfully finalised on 2012-01-31.

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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)

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