LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Dompicare
(domperidone)

SE/H/1273/01/DC

This module reflects the scientific discussion for the approval of Dompicare. The procedure was finalised at 2013-04-17. For information on changes after this date please refer to the module 'Update'.

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.mpa.se E-mail: registrator@mpa.se

I. INTRODUCTION

The application for Dompicare 20 mg film-coated tablet is a hybrid application made according to Article 10(3) of Directive 2001/83/EC. The applicant, NordicInfu Care AB, applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and Finland and Norway as concerned member states (CMS).

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Peridys 10 mg film-coated tablet authorised in France since 1986, with PIERRE FABRE MEDICAMENT as marketing authorisation holder.
The reference product used in the bioequivalence study is Biperidys 20 mg, film-coated tablet from France with PIERRE FABRE MEDICAMENT as marketing authorisation holder.

For approved indications, see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Dompicare is presented in the form of film-coated tablets containing 20 mg of domperidone. The excipients are lactose monohydrate, povidone, maize starch, crospovidone, sodium laurilsulfate, microcrystalline cellulose, hydrogenated castor oil, magnesium stearate and hypromellose. The tablets are packed in PVC/aluminium blisters.

II.2 Drug Substance

Domperidone has a monograph in the Ph Eur.

Domperidone is a white or almost white powder which is practically insoluble in water, soluble in dimethylformamide and slightly soluble in ethanol and in methanol. The structure of domperiodne has been adequately proven and its physico-chemical properties sufficiently described. The route of synthesis is adequately proven.

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

Dompicare film-coated tablets are 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

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

IV. CLINICAL ASPECTS

IV.1 Pharmacokinetics

Bioequivalence was evaluated in one single-dose, two-way crossover study conducted in 36 healthy volunteers, comparing Dompicare 20 mg film-coated tablet with Biperidys 20 mg film-coated tablet under fasting conditions. The study was conducted at Parexel International (South Africa) between 21 Jan and 17 March 2010. Blood samples were collected pre-dose and up to 36 hours post-dose. The study design is considered acceptable. Plasma concentrations of domperidone were determined with a validated LC/MS/MS method. For AUC_{0-t} and C_{max} the 90% confidence interval for the ratio of the test and reference products fell within the conventional acceptance range of 80.00-125.00%. Hence, bioequivalence was demonstrated.

IV.2 Discussion on the clinical aspects

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 a bridging report making reference to Domperidon EG LABO, FR/H/0364/01/MR. The bridging report submitted by the applicant has been found acceptable.

The risk/benefit ratio is considered positive and Dompicare 20 mg film-coated tablet is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Dompicare 20 mg film-coated tablet was successfully finalised on 2013-04-17.

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

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)

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.mpa.se E-mail: registrator@mpa.se