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IRISH MEDICINES BOARD

PUBLIC ASSESSMENT REPORT FOR A MEDICINAL PRODUCT FOR HUMAN USE

Scientific discussion

Panadol Max Strength Cold and Flu Hot Berry with Vitamin C Powder for Oral Solution
Paracetamol 1000 mg
Ascorbic acid 70 mg
PA No 678/11/4

The Public Assessment Report reflects the scientific conclusion reached by the Irish Medicines Board (IMB) at the end of the evaluation process and provides a summary of the grounds for approval of a marketing authorisation for a specific medicinal product for human use. It is made available by the IMB for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of Directive 2001/83/EC, as amended. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the IMB leading to the approval of the medicinal product for marketing in Ireland.

I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the IMB has granted a marketing authorisation for Panadol max strength cold & flu hot berry plus vitamin C powder for oral solution Paracetamol 1000 mg, Ascorbic acid 70 mg, from GlaxoSmithKline Consumer Healthcare (Ireland) Ltd.
for the following indication: 'The relief of symptoms of influenza, feverishness, chills and feverish colds including headache, and aches and pains'.

The application was submitted in accordance with Article 10 a (well established use/bibliographic application) of Directive 2001/83/EC.

The product is not subject to medical prescription and can be supplied through general sale in limited pack sizes in accordance with the regulations for the sale of paracetamol (Medicinal Products (Prescription and Control of Supply) Regulations 2003 and subsequent regulations).

The Summary of Product Characteristics for (SPC) for this medicinal product is available on the IMB's website at http://www.imb.ie

Name of the product	Panadol max strength cold & flu hot berry plus vitamin C powder for oral solution Paracetamol 1000 mg Ascorbic acid 70 mg
Name(s) of the active substance(s) (INN)	Paracetamol, Ascorbic acid
Pharmacotherapeutic classification (ATC code)	N02BE51
Pharmaceutical form and strength(s)	Powder for Oral Solution, 1000/70 Milligram
Marketing Authorisation Number(s) in Ireland (PA)	678/11/4
Marketing Authorisation Holder	Glaxosmithkline Consumer Healthcare Ltd

II QUALITY ASPECTS

II.1. Introduction

This application is for:
Panadol max strength cold & flu hot berry plus vitamin C powder for oral soln
Paracetamol 1000 mg
Ascorbic acid 70 mg

II.2 Drug substance

The active substances are paracetamol and ascorbic acid, both are established active substances described in the EuropeanPharmacopoeia, and is manufactured in accordance with the principles of Good Manufacturing Practice (GMP)

The active substance specifications are considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification has been provided.

II.3 Medicinal product

P.1 Composition

Powder for Oral Solution
Sachets containing a pale pink powder with a characteristic fruity menthol odour.

Composition of the medicinal product (quantity of active and list of excipients by name only, *dilution for homeopathics*)
The sachet contains:

Active substances
Paracetamol 1000 mg
Ascorbic Acid (Ethylcellulose coated) 70 mg
Excipients
Sodium Citrate, anhydrous
Sucrose
Aspartame
Tartaric acid
Berry Fruits flavourburst in-house
(contains menthol)
Euroblend Blackcurrant in-house
(contains carmoisine (E122), sunset yellow (E110) & green S (E142))

P.2 Pharmaceutical Development

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

P.3 Manufacture of the Product

The product is manufactured in accordance with the principles of good manufacturing practice (GMP) at suitably qualified manufacturing sites.

Retrospective studies on similar products and a commitment to validate the manufacturing process according to *note for guidance on Process Validation CPMP/QWP/848/96* has been accepted and the process is considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients*)*

All ingredients either comply with Ph. Eur. or are adequately controlled by the manufacturer's specifications.

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for oral powders, and the tests and control limits are considered appropriate for this type of product.

The analytical methods used are described in sufficient detail and are supported by validation data.

Batch analytical data for a number of batches from the proposed production site(s) have been provided, and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality.

P.6 Packaging material

The product is presented as paper/polyethylene/aluminium foil/polyethylene sachet..

Evidence has been provided that the sachet complies with EU legislation for use with foodstuffs requirements.

P.7 Stability of the Finished Product

Stability data on the finished product in the proposed packaging have been provided in accordance with EU guidelines demonstrating the stability of the product for 3 years when stored at 25°C/60% RH.

II.4 Discussion on Chemical, Pharmaceutical and Biological Aspects

The important quality characteristics of the product are well-defined and controlled. Satisfactory chemical and pharmaceutical documentation has been provided, assuring consistent quality of Panadol max strength cold & flu hot berry plus vitamin C powder for oral solution.

III NON-CLINICAL ASPECTS

III.1 Introduction

The active substances of this combination product (paracetamol and ascorbic acid) have been available on the European/Irish market for many years. Preclinical data have been superseded by clinical experience and no new preclinical data have been submitted.

IV CLINICAL ASPECTS

IV.1 Introduction

Paracetamol and ascorbic acid are well known active substances with established efficacy and tolerability.

The content of the SPC approved during the national procedure support the proposed indications and dosage regimen and is in accordance with that accepted for similar products marketed by Glaxo Smith Kline Consumer Health.

V OVERALL CONCLUSIONS

BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

This combination product contains well-established active ingredients (paracetamol and ascorbic acid) with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.

The MAH has provided written confirmation that systems and services are in place to ensure compliance with their pharmacovigilance obligations.

The IMB, on the basis of the data submitted, considered that Panadol max strength cold & flu hot berry plus vitamin C powder for oral solution Paracetamol 1000 mg, Ascorbic acid 70 mg demonstrated adequate evidence of efficacy for the approved indication as well as a satisfactory risk/benefit profile and therefore granted a marketing authorisation.