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IRISH MEDICINES BOARD

PUBLIC ASSESSMENT REPORT FOR A MEDICINAL PRODUCT FOR HUMAN USE

Scientific discussion

Nicorette Icy White 2 mg & 4 mg Medicated Chewing Gum
NICOTINE RESINATE
PA0330/037/009

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 Nicorette Icy White 2 mg & 4 mg Medicated Chewing Gum, from Mc Neil Healthcare (Ireland) Ltd <MAH>on 6th August 2010. For the treatment of tobacco dependence by relieving nicotine craving and withdrawal symptoms:

- thereby facilitating smoking cessation in smokers motivated to quit.
- helping smokers temporarily abstain from smoking

This application for a marketing authorisation was submitted in accordance with Article 8(3) of Directive 2001/83/EC containing new data relating to the known active substance nicotine resinate.

This product is for supply without a prescription but for sale from pharmacies only.

Name of the product	Nicorette Icy White 2 mg & 4 mg Medicated Chewing Gum
Name(s) of the active substance(s) (INN)	NICOTINE RESINATE
Pharmacotherapeutic classification (ATC code)	NO7B A01
Pharmaceutical form and strength(s)	2 mg & 4 mg Medicated Chewing Gum
Marketing Authorisation Number(s) in Ireland (PA)	PA0330/037/009
Marketing Authorisation Holder	Johnson & Johnson (Ireland) Limited
MRP/DCP No.	Not applicable
Reference Member State	Not applicable
Concerned Member State	Not applicable

II QUALITY ASPECTS

II.1. Introduction

This application is for Nicorette icy white 2mg medicated gum and Nicorette icy white 4mg medicated gum.

II.2 Drug substance

The active substance is nicotine presented as Nicotine resinate Ph. Eur., an established active substance described in the European Pharmacopoeia, and is manufactured in accordance with the principles of Good Manufacturing Practice (GMP)

The active substance specification is 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

2mg presentation: a square, coated, white medicated chewing gum
4mg presentation: a square, coated, cream medicated chewing gum

Composition of the medicinal product

Each medicated chewing gum contains:

	mg/unit
Nicotine resinate Ph. Eur.	10.0
Containing Nicotine	2.0

Excipients

Chewing gum base (1)
Xylitol
Peppermint Oil
Sodium Carbonate (anhydrous)
Sodium hydrogen Carbonate
Acesulfame potassium
Levomenthol.
Magnesium oxide, light.
Winterterfresh
Hypromellose.
Sucralose
Polysorbate 80
Starch, pregelatinised
Titanium dioxide
Carnauba wax
Purified Water

(1) Chewing gum base composition: Calcium carbonate, Ester gums, microcrystalline wax, Isobutylene-isopropene copolymer (butyl rubber), Glycerol monostearate, Polyethylene, Polyvinyl acetate, Polyisobutylene, Butylhydroxytoluene (BHT).

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.

The manufacturing process has been validated according to relevant European and ICH guidelines and the process is considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients)

All ingredients 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 medicated chewing gum, 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 PVC/PVDC/Aluminium blister packed in strips each containing 6, 10 or 15 pieces, supplied in packs of 10, 12, 15, 30, 105 or 210 pieces.
Evidence has been provided, that the blister strip complies with Ph. Eur for use with 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 a temperature not more than 25°C.

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 nicorette icy white 2mg & 4mg medicated gum.

III NON-CLINICAL ASPECTS

III.1 Introduction

This active substance has been available on the European/Irish market since 1978. Preclinical data have been superseded by clinical experience and therefore no preclinical assessment report is available.

IV CLINICAL ASPECTS

IV.1 Introduction

Nicorette Icy White 2 mg & 4 mg Medicated Chewing Gum contains a well known active substance (nicotine resinate) with established efficacy and tolerability.

The applicant sought approval for Nicorette® 2 mg and 4 mg Icy White medicated chewing gum, containing a proposed new flavour, which provides a strong, minty taste.
Nicorette 2 mg and 4 mg gum are to be used for the treatment of tobacco dependence by relieving nicotine craving and withdrawal symptoms as approved for existing licenses for Nicorette Freshmint 2mg Gum and Nicorette Freshmint 4mg Gum. In addition, the application also proposes a statement regarding the effect on dental staining. The company presented two clinical studies and one in-vitro study showing evidence of stain reduction. Based on this evidence application was approved.

The Marketing Authorisation Holder submitted a set of documents describing the Pharmacovigilance System, including information on the availability of an EU Qualified Person for Pharmacovigilance (EU-QPPV) and the means for notification of adverse reaction reports in the EU or from a Third Country.

V OVERALL CONCLUSIONS

BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

Nicorette® 2 mg and 4 mg Icy White medicated chewing gum, containing a proposed new flavour. Nicorette 2 mg and 4 mg gum are to be used for the treatment of tobacco dependence by relieving nicotine craving and withdrawal symptoms as approved for existing licenses for Nicorette Freshmint 2mg Gum and Nicorette Freshmint 4mg Gum. In addition, the marketing authorisation holder presented two clinical studies and one in-vitro study showing evidence of stain reduction, and makes an appropriate statement in the product information. Based on this evidence application was approved.

This application is a national application in line with article 8(3) of 2001/83/EC where the active substance, nicotine, is a known active substance.

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

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