

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Nicorette Freshfruit 4 mg Medicated Chewing Gum

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each medicated chewing gum contains 4 mg nicotine as a resin complex.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Medicated Chewing Gum.

*Product imported from Greece:*

A square, coated, cream chewing gum.

## 4 CLINICAL PARTICULARS

As per PA23490/019/004

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23490/019/004

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Core:

Chewing gum base

Xylitol

Peppermint oil

Anhydrous sodium carbonate

Yellow quinoline lacquer

Acesulfame potassium

Levomenthol

Light magnesium oxide.

Coating:

Xylitol

Tutti frutti flavour

Hydroxypropylmethylcellulose (HPMC, hypromellose)

Sucralose

Polysorbate 80

Quinoline yellow lacquer

Acacia

Titanium dioxide

Carnauba wax.

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product is the date shown on the container and outer carton of the product as marketed in the country of origin.

#### **6.4 Special precautions for storage**

Do not store above 25°C.

#### **6.5 Nature and contents of container**

Blister packed strips each containing 15 pieces supplied in packs of 105 pieces.

#### **6.6 Special precautions for disposal**

No special requirements.

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd,  
Unit 625 Kilshane Avenue,  
Northwest Business Park,  
Ballycoolin,  
Dublin 15,  
Ireland.

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/210/009

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 19<sup>th</sup> July 2024

### **10 DATE OF REVISION OF THE TEXT**