

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Nicorette 4 mg Medicated Chewing-gum

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each piece of mediated chewing gum contains 4 mg nicotine as a resin complex.

### Excipients with known effect:

Butylated hydroxytoluene

Sorbitol

Flavour for smoker (contains Cinnamal, Cinnamyl alcohol, Citral, Citronellol, Eugenol, Geraniol, Isoeugenol, Limonene, Linalool) ethanol

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Medicated Chewing-gum

### *Product imported from France:*

A square, yellow medicated chewing-gum

## 4 CLINICAL PARTICULARS

As per PA23490/019/015

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23490/019/015

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

chewing gum

sorbitol (E420)

70% crystallizable sorbitol

anhydrous sodium carbonate

Sodium bicarbonate

smoking flavor (contains traces of ethanol, cinnamal, cinnamyl alcohol, citral, decitronellol, eugenol, geraniol, isoeugenol, limonene, linalool)

haverstroo flavor

glycerol 85 percent

### 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**

PPA1463/210/008

### **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**