

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Nicorette Invisi 10 mg/16 hours transdermal patch

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Nicotine, 10 mg released over 16 hours use. Each patch is 9.0 cm<sup>2</sup>, containing 1.75 mg nicotine/cm<sup>2</sup>.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Transdermal Patch.

*Product imported from France*

Beige, semi-transparent transdermal patch consisting of a backing layer, a nicotine source layer, a skin contact adhesive layer and a siliconised and aluminised release layer, with "nicorette" printed on the top face of the patch.

## 4 CLINICAL PARTICULARS

As per PA0330/037/005

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0330/037/005

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Polyethylene terephthalate (PET) film  
Triglycerides, medium-chain  
Basic butyl methacrylate copolymer

#### **Acrylate matrix**

Acrylic copolymer adhesive solution  
Potassium hydroxide  
Croscarmellose sodium  
Aluminium acetylacetonate

#### **Release layer**

Polyethylene terephthalate (PET) film single side aluminised, both sides siliconised

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the sachet 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**

Heat-sealed laminate pouch containing one patch.  
Carton of 7 patches.

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

Nicotine residues in used patches may present a hazard to children and pets, thus used patches should be folded, sticky sides together, put back in an empty pouch and placed in household rubbish.

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

PCO Manufacturing Ltd.,  
Unit 10,  
Ashbourne Business Park,  
Rath,  
Ashbourne,  
Co. Meath,  
Ireland

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

PPA0465/187/007

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

Date of first authorisation date: 5<sup>th</sup> August 2022

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