

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Solpadol Caplets 500mg/30mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Paracetamol 500.0 mg

Codeine Phosphate Hemihydrate 30.0 mg

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet.

*Product imported from: UK*

White to off-white, capsule-shaped tablets with flat sides, marked 'SOLPADOL' on one side and blank on the reverse.

## 4 CLINICAL PARTICULARS

As per PA0540/159/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0540/159/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Pregelatinised starch

Maize starch

Povidone

Potassium sorbate

Microcrystalline cellulose

Stearic acid

Talc

Magnesium stearate

Croscarmellose sodium (Type A)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blisters 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.

Store in the original package in order to protect from moisture.

### 6.5 Nature and contents of container

Blisters in a cardboard outer carton.

Pack size: 100

**6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9  
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/191/001

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

Date of first authorisation: 28<sup>th</sup> February 2014

**10 DATE OF REVISION OF THE TEXT**

October 2019