Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Solpadol 500mg/30mg Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Paracetamol	500.0 mg
Codeine Phosphate Hemihydrate	30.0 mg

Excipients of known effect: sorbitol (E420) and sodium
For a full list of excipeints see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent Tablet.
Product imported from: UK
A white bevelled-edge tablet scored on one face and plain on the reverse.

4 CLINICAL PARTICULARS

As per PA0540/159/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/159/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric Acid Anhydrous
Saccharin Sodium
Povidone
Sodium Bicarbonate
Sodium Carbonate Anhydrous
Sorbitol Powder (E420)
Sodium Laurilsulfate
Dimeticone

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the laminate strips 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

Strips of 10 tablets 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 Ltd
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/191/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th February 2014

10 DATE OF REVISION OF THE TEXT

December 2014