# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Transtec 70 micrograms/h Transdermal Patch

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One transdermal patch contains 40 mg buprenorphine.
Area containing the active substance: 50 $cm^2$
Nominal release rate: 70 micrograms of buprenorphine per hour (over a period of 96 hours).
For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Transdermal Patch

*Product imported from* Italy:
Skin coloured patch with rounded corners marked:
Transtec 70µg/h, buprenorphinium 40mg

## 4 CLINICAL PARTICULARS

As per PA1032/001/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1032/001/003

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

*Adhesive matrix (containing buprenorphine):* [(Z)-octadec-9-en-1-yl] oleate, povidone K90, 4-oxopentanic acid, poly [acrylic acid-co-butylacrylate-co-(2-ethylhexyl)acrylate-co-vinylacetate] (5:15:75:5), cross-linked

*Adhesive matrix (without buprenorphine):* poly[acrylic acid-co-butylacrylate-co-(2-ethylhexyl)acrylate-co-vinylacetate] (5:15:75:5), not cross-linked

*Separating foil between the adhesive matrices with and without buprenorphine:* poly(ethyleneterephthalate) – foil

*Backing layer:* poly(ethyleneterephthalate) – tissue

*Release liner (on the front covering the adhesive matrix containing buprenorphine):* poly(ethyleneterephthalate) – foil, siliconised, coated on one side with aluminium.

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

## 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

## 6.5 Nature and contents of container

*Type of container:*
Sealed sachet, composed of identical top and bottom layers of heat-sealable laminate, comprising (from outside to inside) paper.
*Pack sizes:*
Packs containing 4 individually sealed transdermal patches.

## 6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

# 7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

# 8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/315/003

# 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd May 2014

# 10 DATE OF REVISION OF THE TEXT

October 2016