Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Transtec 52.5 micrograms/h Transdermal Patch

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One transdermal patch contains 30 mg buprenorphine.
Area containing the active substance: 37.5 cm^2
Nominal release rate: 52.5 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 transdermal patch with rounded corners marked:
Transtec 52.5µg/h, buprenorphinium 30mg.

4 CLINICAL PARTICULARS

As per PA1032/001/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1032/001/002

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

PPA0465/315/002

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