Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Durogesic DTrans 12 micrograms/hour Transdermal Patch

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Durogesic DTrans 12 patch contains fentanyl 2.1 mg.
Release rate of approximately 12 micrograms per hour; active surface area 5.25 cm^2.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Transdermal patch

Product imported from Italy and Greece
Durogesic is a translucent, rectangular transdermal patch with rounded corners, marked with the product name, strength and a border in coloured ink.

The patch has a sticky back so that it can be stuck onto the skin.

Each patch is marked:
Durogesic
12 µg fentanyl/h

Orange printing ink

4 CLINICAL PARTICULARS

As per PA22612/004/005

5 PHARMACOLOGICAL PROPERTIES

As per PA22612/004/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyacrylate adhesive
Polyethylene terephthalate/ethyl vinyl acetate film
Orange printing ink
Siliconised polyester film

6.2 Incompatibilities

To prevent interference with the adhesive properties of Durogesic DTrans, no creams, oils, lotions or powder should be applied to the skin area when the Durogesic DTrans transdermal patch is applied.

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 temperature storage conditions. Store in the original pouch in order to protect from light.

6.5 Nature and contents of container

Each patch is packed in a heat-sealed pouch made of acrylonitrate film, polyethylene terephthalate (PET), low density polyethylene/aluminium foil and adhesive.
Pouches are packed into cardboard cartons (five pouches per carton).

6.6 Special precautions for disposal and other handling

Instructions for disposal:
Used patches should be folded so that the adhesive side of the patch adheres to itself and then they should be safely discarded. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/314/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th April 2015

10 DATE OF REVISION OF THE TEXT

January 2024