Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Durogesic DTrans 50 micrograms/hour Transdermal Patch

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Durogesic DTrans 50 patch contains fentanyl 8.4 mg.
Release rate of approximately 50 micrograms per hour; active surface area 21.0 cm^2.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Transdermal patch.

Product imported from Italy, Greece and Poland
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 21.0 cm^2 and is marked with a border and "Durogesic 50 µg fentanyl/h" in green printing ink.

4 CLINICAL PARTICULARS

As per PA22612/004/002

5 PHARMACOLOGICAL PROPERTIES

As per PA22612/004/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyacrylate adhesive
Polyethylene terephthalate/ethyl vinyl acetate film
Green 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

PPA0465/314/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th July 2014

10 DATE OF REVISION OF THE TEXT

January 2024