

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Durogesic DTrans 100 micrograms/hour Transdermal Patch

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Durogesic DTrans 100 patch contains fentanyl 16.8 mg.

Release rate of approximately 100 micrograms per hour; active surface area 42.0 cm².

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Transdermal patch

Product imported from Poland

Durogesic is a translucent, rectangular transdermal patch with rounded corners, marked with the product name, strength and a border in grey coloured ink.

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

Each patch is marked:

Durogesic

100 µg fentanyl/h

4 CLINICAL PARTICULARS

As per PA0748/002/004

5 PHARMACOLOGICAL PROPERTIES

As per PA0748/002/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyacrylate adhesive

Polyethylene terephthalate/ethyl vinyl acetate film

Grey 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 is the date shown on the patch pouch and outer carton of the product as marked in the country of origin

6.4 Special precautions for storage

This medicinal product does not require any other special storage precautions.

6.5 Nature and contents of container

Cardboard outer carton containing patches.

Pack size: 5 Patches

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

Imbat Ltd.,
Unit L2,
North Ring Business Park,
Santry,
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/252/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 23rd October 2015

10 DATE OF REVISION OF THE TEXT

January 2018