

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Durogesic DTrans 25 micrograms/hour Transdermal Patch

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Durogesic DTrans 25 patch contains fentanyl 4.2 mcg.

Release rate of approximately 25 micrograms per hour; active surface area 10.5 cm².

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Transdermal Patches

Product imported from Poland

Translucent rectangular patch with rounded corners, marked with product name, strength and a border in red coloured ink.

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

Each patch is marked

Durogesic®

25 µg fentanyl/h.

4 CLINICAL PARTICULARS

As per PA 0748/002/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 0748/002/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyacrylate adhesive

Polyethylene terephthalate/ethyl vinyl acetate film

Red 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

Please refer to Section 4.2 of PA0748/002/001 for instructions on how to apply the patch. There are no safety and pharmacokinetic data available for other application sites.

Used patches should be folded so that the adhesive side of the patch adheres to itself and then they should be safely discarded. Unused patches should be returned to the (hospital) pharmacy.

Wash hands with only water after applying or removing the patch.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/252/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 23rd October 2015

10 DATE OF REVISION OF THE TEXT

September 2017