

## 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 8.4mg

Release rate of approximately 50 micrograms per hour; active surface area 21.0 cm<sup>2</sup>.

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 green coloured ink.

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

Each patch is marked

Durogesic

50 µg fentanyl/h

### 4 CLINICAL PARTICULARS

As per PA0748/002/002

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0748/002/002

### 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 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 conditions.

#### **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**

PPA1151/252/001

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 13<sup>th</sup> November 2015

### **10 DATE OF REVISION OF THE TEXT**

January 2018