

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Actiq 400 micrograms compressed lozenge with integral oromucosal applicator

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One lozenge contains 400 micrograms fentanyl (as citrate).

### Excipients with known effect:

Each lozenge contains glucose and sucrose.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Compressed lozenge with integral oromucosal applicator.

### *Product imported from Italy and Greece*

Actiq is formulated as a white to off-white compressed powder medicinal product matrix attached using edible glue to a fracture resistant radio opaque plastic applicator. The dosage strength is marked on the lozenge and on the plastic applicator.

## 4 CLINICAL PARTICULARS

As per PA0749/195/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0749/195/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### *Product imported from Italy*

##### **Lozenge:**

Dextrates hydrated (equivalent to about 1.89 grams of glucose)

Citric acid, anhydrous

Disodium phosphate, anhydrous

Artificial berry flavour (maltodextrin, propylene glycol, artificial flavours and triethylcitrate)

Magnesium stearate

##### **Edible glue used to attach the lozenge to the handle:**

Modified maize based food starch (E 1450)

Confectioner's sugar (sucrose and maize starch)

Water, purified

##### **Imprinting ink:**

De-ionised water

De-waxed white shellac

Propylene glycol

Blue synthetic coal tar dye (E 133)

Ammonium hydroxide (E 527) for pH adjustment

#### *Product imported from Greece*

##### **Lozenge:**

Dextrates hydrated (equivalent to about 1.89 grams of glucose)

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Citric acid  
Disodium phosphate  
Artificial berry flavour (maltodextrin, propylene glycol, artificial flavours and triethylcitrate)  
Magnesium stearate

**Edible glue used to attach the lozenge to the handle:**

Modified maize based food starch (E 1450)  
Confectioner's sugar (as sucrose and maize starch)  
Water

**Imprinting ink:**

Water  
De-waxed white shellac  
Propylene glycol  
Blue synthetic coal tar dye (E 133)  
Ammonium hydroxide (E 527) for pH adjustment

**6.2 Incompatibilities**

Not applicable.

**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**

Do not store above 30°C.

Store in protective blister until ready to use.

**6.5 Nature and contents of container**

Each Actiq dosage unit is contained in a heat sealed blister package consisting of a paper/foil laminated lid, and a thermoformed blister, supplied in cartons of 15 or 30 individual units.

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

Lozenges with residual active substance should at no time be discarded or misplaced. Any used or unused but no longer required 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**

PPA0465/407/002

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

Date of first authorisation: 15<sup>th</sup> May 2015

**10 DATE OF REVISION OF THE TEXT**

March 2024