Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Actiq 200 micrograms compressed lozenge with integral oromucosal applicator

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One lozenge contains 200 micrograms fentanyl (as citrate).

Excipientswith 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 PA0749/195/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0749/195/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from Italy
Lozenge:
Dextrates hydrated (containing 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 (E1450)
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 (E133)

Product imported from Greece
Lozenge:
Dextrates hydrated (equivalent to about 2 grams of glucose)
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 E133

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 heatsealed blister package consisting of a paper/foil laminated lid, and athermoformed blister, supplied in cartons of 15 or 30 individual units. Not allpack 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

PPA0465/407/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th of May 2015

10 DATE OF REVISION OF THE TEXT

August 2021