

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Concerta XL 36 mg prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One prolonged-release tablet contains 36 mg of methylphenidate hydrochloride.
Excipients with known effect: contains lactose.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablet.

Product imported from Greece

Capsule-shaped, white tablet with “alza 36” printed on one side in black ink.

4 CLINICAL PARTICULARS

As per PA0748/049/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0748/049/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene (E321)
Cellulose acetate
Hydroxypropylmethylcellulose (E464)
Phosphoric acid concentrated
Poloxamer 188
Polyethylene oxides 200K and 7000K
Povidone K29-32
Sodium chloride
Stearic acid
Succinic acid
Iron oxide black (E172)
Iron oxide yellow (E172)

Film Coat

Hydroxypropylmethylcellulose (E464)
Lactose monohydrate
Titanium dioxide (E171)
Triacetin

Clear Coat

Carnauba wax
Hydroxypropylmethylcellulose (E464)
Macrogol 400

Printing Ink

Iron oxide black (E172)
Hypromellose (E464)
Isopropyl alcohol
Propylene glycol
Purified water

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

Keep the bottle tightly closed to protect from moisture.
Do not store above 30°C.

6.5 Nature and contents of container

Bottle with a child-resistant polypropylene closure with one or two silica gel desiccant pouches enclosed.
30 prolonged-release tablets.

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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10 Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/417/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th November 2015

10 DATE OF REVISION OF THE TEXT