Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Concerta XL 18 mg prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One prolonged-release tablet contains 18 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 Germany
Capsule-shaped, yellow tablets with “alza 18” printed on one side in black ink.

4 CLINICAL PARTICULARS

As per PA0748/049/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0748/049/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene (E321)
Cellulose acetate
Hypromellose (E464)
Phosphoric acid 85%
Poloxamer 188
Macrogol 200 000 and 7000 000
Povidone K29-32
Sodium chloride
Stearic acid
Succinic acid
Iron oxide black (E172)
Iron oxide yellow (E172)

Film coat:
Iron oxide yellow (E172)
Hypromellose (E464)
Lactose monohydrate
Stearic acid
Titanium dioxide (E171)
Triacetin

Clear coat:
Carnauba wax
Hypromellose (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 is the date shown on the inner packaging and outer carton of the product as marked in the country of origin.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Cardboard outer containing a high-density polyethylene (HDPE) bottle with a child-resistant polypropylene closure with one or two silica gel desiccant pouches enclosed.

Pack size: 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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/243/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd April 2015

10 DATE OF REVISION OF THE TEXT