Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zithromax Capsules 250 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 250 mg of azithromycin (as dihydrate)

Excipients with known effect:
anhydrous lactose - see leaflet for further information.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule

Product imported from Spain
White, capsules marked with ‘Pfizer’ and ‘ZTM 250’ on the cap and body.

4 CLINICAL PARTICULARS

As per PA0019/047/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0019/047/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule Contents
Anhydrous lactose
Magnesium stearate
Sodium lauryl sulphate
Corn starch (without gluten)

Capsule Shell
Gelatin
Titanium dioxide (E171)

Printing Ink
Black ink composed of (shellac) 45%, black iron oxide (E172), propylene glycol and ammonium hydroxide 28% or lacquer (Shellac), black iron oxide (E172), propylene glycol, strong solution of ammonium and potassium hydroxide.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister strip and outer carton of the product as marked in the country of origin.

6.4 Special precautions for storage

Do not store above 30ºC.
Do not refrigerate. Store in the original carton.

6.5 Nature and contents of container

Cardboard outer carton containing blister strip.
Pack size: 6 capsules.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/237/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th November 2014

10 DATE OF REVISION OF THE TEXT