

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zithromax Capsules 250mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Azithromycin dihydrate equivalent to 250 mg azithromycin.

Excipients with known effect:
Each capsule contains lactose

Product imported from the UK also includes: sulphur dioxide.
Product imported from Spain also includes: soya lecithin

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, Hard

Product imported from the UK:

White, hard capsule with “Pfizer” printed on one side and “ZTM 250” on the other.

Product imported from Spain:

White, hard capsules with “Pfizer” and “ZTM 250” printed in black.

4 CLINICAL PARTICULARS

As per PA0019/047/001.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in Section 6.1. The product imported from Spain contains soya lecithin. Soya lecithin may be a source of soya protein and should therefore not be taken in patients allergic to soya or peanut due to the risk of hypersensitivity reactions.

4.4 Special warnings and precautions for use

The product imported from the UK contains sulphur dioxide. Sulphur dioxide may rarely cause hypersensitivity reactions and bronchospasm.

5 PHARMACOLOGICAL PROPERTIES

As per PA0019/047/001.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from the UK:

Lactose anhydrous
Magnesium stearate
Maize starch
Sodium lauryl sulphate
Gelatin
Titanium dioxide (E171)
Black iron oxide (E172)
Shellac
Sulphur Dioxide.

Product imported from Spain:

Lactose anhydrous
Magnesium stearate
Maize starch
Sodium Lauryl sulphate
Gelatin
Titanium dioxide (E171)

Printing ink:

Soya lecithin
Black iron oxide (E172)
Antifoam DC 1510
N-butyl alcohol
Industrial methylated spirit 74 OP special inks and shellac

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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.
Do not refrigerate.
Store in the original container.

6.5 Nature and contents of container

Blister pack of 6 capsules contained in an outer cardboard carton.

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

PPA0465/139/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th November 2004

Date of last renewal: 26th November 2009

10 DATE OF REVISION OF THE TEXT

September 2016