Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zinnat 500 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg cefuroxime as cefuroxime axetil.
Excipients with known effect: parahydroxybenzoates

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Austria

White to off-white biconvex capsule shaped tablet, plain on one face and with the code ‘GXEG2’ engraved on the reverse.

4 CLINICAL PARTICULARS

As per PA1077/015/004

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/015/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
microcrystalline cellulose
croscarmellose sodium
sodium lauryl sulphate
hydrogenated vegetable oil
colloidal silicon dioxide

Film-coat
hypromellose
propylene glycol
methyl-4-hydroxybenzoate E218
propyl-4-hydroxybenzoate E216
Opaspray white M-1-7120 (hypromellose, titanium dioxide E171, E211 sodium benzoate, industrial methlated spirits 74 OP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Zinnat tablets are packed in double aluminium & aluminium/paper foil blisters of 14 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

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/163/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd September 2015

10 DATE OF REVISION OF THE TEXT