Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Augmentin 875 mg/125 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains amoxicillin trihydrate equivalent to 875 mg amoxicillin and potassium clavulanate equivalent to 125 mg of clavulanic acid.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the Czech Republic
White to off-white, capsule shaped tablets debossed with “AC” on both sides and a score line on one side.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA1077/019/005

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/019/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Magnesium stearate
Sodium carboxymethyl starch (Type A)
Colloidal anhydrous silica
Microcrystalline cellulose

Tablet film-coat
Titanium dioxide (E171)
Hypromellose (2506/5, 2506/15)
Macrogol (4000, 6000)
Dimeticone

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

Tablets in desiccated pouch packs should be used within 30 days of opening.

6.4 Special precautions for storage

Do not store above 25ºC
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Blister enclosed within a pouch containing a dessicant sachet, referred to as a desiccated pouch pack (DPP) containing 14 tablets.

6.6 Special precautions for disposal and other handling

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon (UK) Ltd
Unit 18
Oxleasow Road
East Moons Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/043/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th March 2018

10 DATE OF REVISION OF THE TEXT