

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Augmentin - Duo 400 mg/57 mg/5 ml Powder for Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

When reconstituted, every ml of oral suspension contains amoxicillin trihydrate equivalent to 80 mg amoxicillin and potassium clavulanate equivalent to 11.4 mg of clavulanic acid.

Each 5ml of reconstituted suspension contains amoxicillin trihydrate equivalent to 400mg amoxicillin and potassium clavulanate equivalent to 57mg clavulanic acid.

Excipients: contains 3.32 mg of aspartame (E951) and maltodextrin

For a full list of excipients see Section 6.1

3 PHARMACEUTICAL FORM

Powder for Oral Suspension.

Product imported from Portugal and Romania:

White powder for reconstitution in water, at time of dispensing, to form an oral sugar-free suspension.

4 CLINICAL PARTICULARS

As per PA1077/019/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/019/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Crospovidone
Carmellose sodium
Xanthan gum
Colloidal anhydrous silica
Magnesium stearate
Sodium benzoate (E211)
Aspartame (E951)
Strawberry flavour (contains maltodextrin)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

Reconstituted suspensions should be stored at 2-8°C (but not frozen) for up to seven days.

6.4 Special precautions for storage

Store in the original package in order to protect from moisture.

The dry powder should be stored in the original container.

Do not store above 25°C.

For storage instructions for the reconstituted suspension please see Section 6.3.

6.5 Nature and contents of container

Clear, glass bottle containing powder for reconstitution to 35 ml or 70 ml. This may be supplied with a plastic measuring spoon or plastic measuring cup or dosing syringe.

Not all pack sizes may be marketed.

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

Check cap seal is intact before using. Shake bottle to loosen powder. Add volume of water (as indicated below) invert and shake well. Alternatively fill the bottle with water to just below the mark on bottle label, invert and shake well, then top up with water exactly to the mark, invert and again shake well.

<u>Strength</u>	<u>Volume of water to be added at reconstitution (ml)</u>	<u>Final volume of reconstituted oral suspension (ml)</u>
400 mg/57 mg/5 ml	32	35
400 mg/57 mg/5 ml	64	70
400 mg/57 mg/5 ml	127	140

Shake the bottle well before each dose.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Primecrown 2010 Ltd.
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/017/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 02nd March 2012

10 DATE OF REVISION OF THE TEXT

November 2016