

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients: Aspartame (E951), Maltodextrin (dextrose)

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral suspension.

Product imported from Portugal and Italy:

Dry powder for reconstitution with off-white grains and a characteristic odour.

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

Pack size 70ml also contains silicon dioxide

Pack size 35ml also contains hydrated colloidal silica

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.

After reconstitution suspension should be stored in a refrigerator between 2-8°C, and used within 7 days.

6.4 Special precautions for storage

Dry powder: Do not store above 25°C. Keep the container tightly closed.

Store in the original package

Reconstituted suspension: Store in a refrigerator (2°C - 8°C.) Do not freeze.

6.5 Nature and contents of container

Clear, glass bottles containing sufficient powder to provide 35ml or 70ml reconstituted suspension.

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 black arrow (that has "Livello Liquido" for pack size 35ml) marked on the 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>
400mg/57mg/5ml	32	35
400mg/57mg/5ml	64	70

Shake the bottle well before each dose.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/050/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 11th July 2007

10 DATE OF REVISION OF THE TEXT

June 2015