

製造廠名稱變更 藥商名稱變更 處方變更

行政院衛生署藥品許可證

衛生署藥輸字第 022447 號

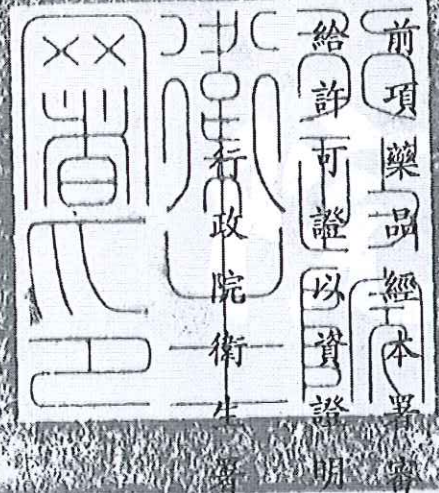
中文名稱：安滅菌糖漿用粉劑 7 簽署文件號碼：DHA00202244705
英文名稱：Augmentin Syrup 457mg/5ml 4 5 公絲 / 5 公撮

類別：本藥須由醫師處方使用 藥商名稱：荷蘭史克美占遠東股份有限公司 臺灣分公司
劑型：糖漿用粉劑 製造廠名稱：Smithkline Beecham Pharmaceuticals (P) Clarendon Road, Worthing, West Sussex, United Kingdom, BN14 8QH. (O)SB House, Great West Road, Brentford, Middlesex, United Kingdom, TW8 9BD.

包裝種類：2.5公撮單一劑量袋裝、製造廠地址：1000公撮以下瓶裝附量
處方：器。

Each ml contains:
Amoxycillin trihydrate equivalent to amoxycillin.....80mg
Potassium clavulanate equivalent to clavulanic acid.....11.4mg

適應症：葡萄球菌、鏈球菌、肺炎雙球菌、腦膜炎球菌及其他具有感受性細菌引起之感染症。



前項藥品經本署審核與藥事法之規定相符應發

署長

唐浩賢

發證日期 捌拾捌年 肆月 捌日
有效期間 玖拾參年 肆月 捌日

至延展核准



中華民國七十八年四月八日

09303 藥衛



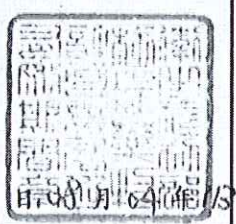
中華民國八十三年八月八日

09803 藥衛



中華民國八十四年八月八日

10260148 藥衛



中華民國八十五年八月八日

1076037 藥衛

| 負責人蓋章 | 核准文號 | 核准日期 | 負責人蓋章 | 核准文號 | 核准日期 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---------------|------|-------|------|------|----------------------|---------------|--------------------|--------|--|-------|---|-------|-------------------|-------|-------------|-------|-----------|------|---------------|-------|------------------|-------|------------------------------|-------|----------------------|-------|----------------------|-------|-----------------------|-------|--------------------------|-------|-----------------|-----------|
| <p>製造廠名稱變更 SmithKline Beecham Plc</p> <p>藥商名稱變更 荷蘭葛蘭史克藥廠股份有限公司台灣分公司</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>變更事項</p> <p>處方變更</p> <table border="1"> <thead> <tr> <th>Existing formulation</th> <th>Quantity (mg)</th> </tr> </thead> <tbody> <tr> <td>Active ingredients</td> <td>400.00</td> </tr> <tr> <td>Amoxicillin Trihydrate equivalent to amoxicillin</td> <td>57.00</td> </tr> <tr> <td>Potassium Citrate equivalent to citric acid</td> <td>57.00</td> </tr> <tr> <td>Other ingredients</td> <td>12.50</td> </tr> <tr> <td>Xanthan Gum</td> <td>12.50</td> </tr> <tr> <td>Aspartame</td> <td>0.84</td> </tr> <tr> <td>Succinic acid</td> <td>24.00</td> </tr> <tr> <td>Colloidal silica</td> <td>79.55</td> </tr> <tr> <td>Hydroxypropylmethylcellulose</td> <td>15.00</td> </tr> <tr> <td>Orange dry flavour 1</td> <td>11.25</td> </tr> <tr> <td>Orange dry flavour 2</td> <td>22.50</td> </tr> <tr> <td>Raspberry dry flavour</td> <td>22.50</td> </tr> <tr> <td>Garden spray dry flavour</td> <td>22.75</td> </tr> <tr> <td>Silicon dioxide</td> <td>79.900.00</td> </tr> </tbody> </table> | | | | | | Existing formulation | Quantity (mg) | Active ingredients | 400.00 | Amoxicillin Trihydrate equivalent to amoxicillin | 57.00 | Potassium Citrate equivalent to citric acid | 57.00 | Other ingredients | 12.50 | Xanthan Gum | 12.50 | Aspartame | 0.84 | Succinic acid | 24.00 | Colloidal silica | 79.55 | Hydroxypropylmethylcellulose | 15.00 | Orange dry flavour 1 | 11.25 | Orange dry flavour 2 | 22.50 | Raspberry dry flavour | 22.50 | Garden spray dry flavour | 22.75 | Silicon dioxide | 79.900.00 |
| Existing formulation | Quantity (mg) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Active ingredients | 400.00 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Amoxicillin Trihydrate equivalent to amoxicillin | 57.00 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Potassium Citrate equivalent to citric acid | 57.00 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Other ingredients | 12.50 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Xanthan Gum | 12.50 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Aspartame | 0.84 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Succinic acid | 24.00 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Colloidal silica | 79.55 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hydroxypropylmethylcellulose | 15.00 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Orange dry flavour 1 | 11.25 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Orange dry flavour 2 | 22.50 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Raspberry dry flavour | 22.50 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Garden spray dry flavour | 22.75 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Silicon dioxide | 79.900.00 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Reference | Quantity |
|-----------------------------------|-----------|
| Active ingredients | 400.00 |
| Amoxicillin Trihydrate equivalent | 57.00 |
| Potassium Citrate equivalent | 57.00 |
| In dextrose acid | 67.00 |
| Other ingredients | 12.50 |
| Xanthan Gum | 12.50 |
| Aspartame | 0.84 |
| Succinic acid | 24.00 |
| Colloidal silica | 79.55 |
| Hydroxypropylmethylcellulose | 15.00 |
| Orange dry flavour 1 | 11.25 |
| Orange dry flavour 2 | 22.50 |
| Raspberry dry flavour | 22.50 |
| Garden spray dry flavour | 22.75 |
| Silicon dioxide | 79.900.00 |

包裝

1000 公撮以下 (附內襯為 PE 成分之鋁製螺旋蓋)
瓶裝附量器、2.5 公撮單一劑量袋裝

100 公撮以下

中文品名變更

安滅菌藥用粉劑 457 毫克/5 毫升

大瓶包裝廠地址變更

桃園市大園區和平里 1 鄰開和路 91 號

1076000783

107.2.08

新增包裝廠：
裕利股份有限公司 (桃園市大園區 337 和平村 1 鄰舊厝子 1-2 號)

製造廠名稱變更為：

SmithKline Beecham Pharmaceuticals

全處方變更為：

主成分：
AMOXICILLIN (TRIHYDRATE).....459.17mg
CLAVULANATE POTASSIUM.....67.90mg

賦形劑：

XANTHAN GUM.....12.50mg
ASPARTAME.....12.50mg
SILICON DIOXIDE ANHYDROUS... 169.94mg
HYDROXYPROPYLMETHYLCELLULOSE 79.55mg
SUCCLINIC ACID.....0.84mg
COLLOIDAL ANHYDROUS SILICA... 25.00mg
GOLDEN STRIP DRY FLAVOUR... 22.75mg
RASPBERRY DRY FLAVOUR.....22.50mg
ORANGE DRY FLAVOUR 1.....15.00mg
ORANGE DRY FLAVOUR 2.....11.25mg

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