



荷商葛蘭素史克藥廠股份有限公司台灣分公司 書函

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受文者：裕利股份有限公司/吉程股份有限公司/裕翔藥
品股份有限公司

發文日期：中華民國 112 年 5 月 25 日
發文字號：GSK 112064 號

主 旨：通知本公司藥品衛署藥輸字第024256號「克憂果持續性藥效錠12.5毫克/ SEROXAT CR TABLETS 12.5MG」外盒、標籤、仿單變更事宜，並請協助轉知各使用之醫療單位、中華民國藥師公會全國聯合會、社團法人台灣臨床藥學會及台灣年輕藥師協會。

說 明：

- 一、藥商地址樓層由24樓變更為23樓、商標符號及年分更新為2022年。
- 二、因應上述之成品製造廠名稱、藥商地址變更，其外盒、仿單一併更新為新廠名、新藥商地址，請見下述之變更前後對照表：



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GlaxoSmithKline Far East B.V. Taiwan Branch

24F, No. 66, Sec 1, Zhong Xiao W. Rd., Taipei 100, Taiwan
Tel: 886-2-23818866 Fax: 886-2-23120838

GSK

外盒 變更前:

正面:



The front of the Seroxat CR box features the GSK logo in the top right corner. The product name 'Seroxat' is in blue, followed by 'CR' in a white circle. Below this, it states '12.5 mg controlled release tablets paroxetine hydrochloride Oral use 30 tablets'. To the right, the Chinese name '克憂果' is prominently displayed, followed by '12.5毫克持續性藥效錠'. Further right, there is a block of Chinese text providing regulatory information: '本藥須由醫師處方使用', '衛署藥輸字第024256號', '藥商: 荷蘭葛蘭素史克藥廠股份有限公司 台灣分公司', '地址: 台北市忠孝西路一段66號24樓', '廠名: BORA PHARMACEUTICAL SERVICES INC.', and '廠址: 7333 MISSISSAUGA ROAD, MISSISSAUGA, ONTARIO CANADA, L5N 6L4'.

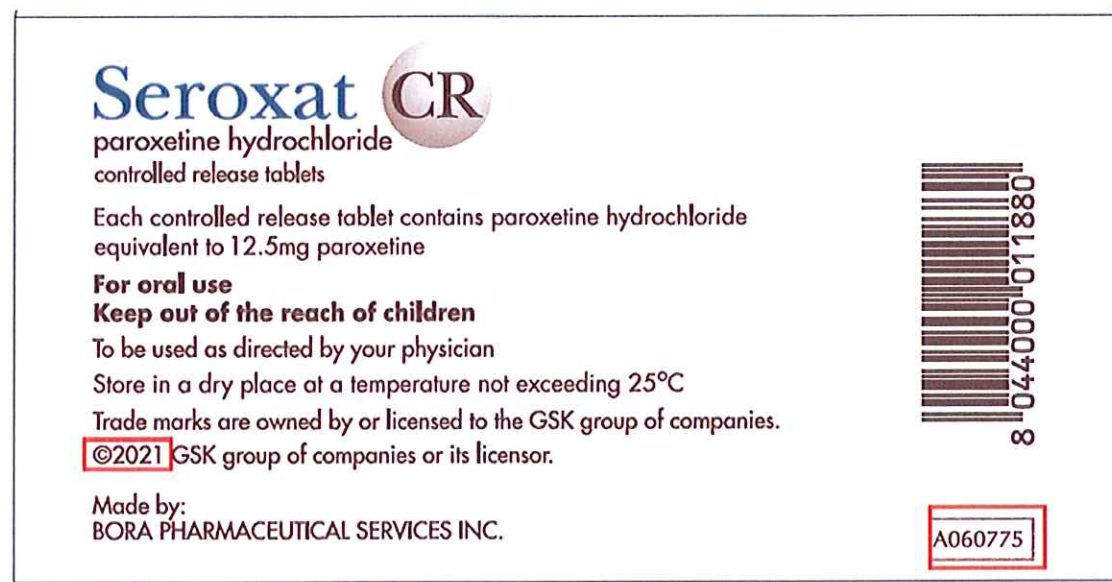
Seroxat CR

12.5 mg controlled release tablets
paroxetine hydrochloride
Oral use
30 tablets

克憂果
12.5毫克持續性藥效錠

本藥須由醫師處方使用
衛署藥輸字第024256號
藥商: 荷蘭葛蘭素史克藥廠股份有限公司
台灣分公司
地址: 台北市忠孝西路一段66號24樓
廠名: BORA PHARMACEUTICAL
SERVICES INC.
廠址: 7333 MISSISSAUGA ROAD
MISSISSAUGA, ONTARIO CANADA,
L5N 6L4

背面:



The back of the Seroxat CR box contains detailed usage and storage instructions. It starts with the product name 'Seroxat CR' and 'paroxetine hydrochloride controlled release tablets'. It states 'Each controlled release tablet contains paroxetine hydrochloride equivalent to 12.5mg paroxetine'. Key instructions include 'For oral use', 'Keep out of the reach of children', 'To be used as directed by your physician', and 'Store in a dry place at a temperature not exceeding 25°C'. It also mentions 'Trade marks are owned by or licensed to the GSK group of companies.' and '©2021 GSK group of companies or its licensor.' At the bottom left, it says 'Made by: BORA PHARMACEUTICAL SERVICES INC.'. On the right side, there is a vertical barcode with the number '8 044000 011880' and a small box at the bottom right containing the code 'A060775'.

Seroxat CR
paroxetine hydrochloride
controlled release tablets

Each controlled release tablet contains paroxetine hydrochloride equivalent to 12.5mg paroxetine

For oral use
Keep out of the reach of children
To be used as directed by your physician
Store in a dry place at a temperature not exceeding 25°C
Trade marks are owned by or licensed to the GSK group of companies.
©2021 GSK group of companies or its licensor.

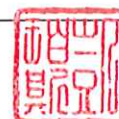
Made by:
BORA PHARMACEUTICAL SERVICES INC.

8 044000 011880
A060775

第 2 / 5 頁

GlaxoSmithKline Far East B.V. Taiwan Branch

24F, No. 66, Sec 1, Zhong Xiao W. Rd., Taipei 100, Taiwan
Tel: 886-2-23818866 Fax: 886-2-23120838





變更後:

正面

The front of the Seroxat CR box features the GSK logo in the top right corner. The product name 'Seroxat' is in blue, and 'CR' is in a purple circle. Below this, it says '12.5 mg controlled release tablets paroxetine hydrochloride Oral use 30 tablets'. To the right, the Chinese name '克憂果' is prominently displayed, followed by '12.5毫克持續性藥效錠'. Further down, there is a block of Chinese text providing usage instructions, regulatory numbers, and the manufacturer's details: BORA PHARMACEUTICAL SERVICES INC. in Mississauga, Ontario, Canada.

Seroxat CR
12.5 mg controlled release tablets
paroxetine hydrochloride
Oral use
30 tablets

克憂果
12.5毫克持續性藥效錠

本藥須由醫師處方使用
衛署藥輸字第024256號
藥商:荷商葛蘭素史克藥廠股份有限公司
台灣分公司
地址:台北市忠孝西路一段66號23樓
廠名:BORA PHARMACEUTICAL
SERVICES INC.
廠址:7333 MISSISSAUGA ROAD
MISSISSAUGA, ONTARIO CANADA,
L5N 6L4

背面

The back of the Seroxat CR box contains detailed usage and storage information. It includes the product name 'Seroxat CR' and 'paroxetine hydrochloride controlled release tablets'. A paragraph states that each tablet contains 12.5mg of paroxetine. Key instructions include 'For oral use', 'Keep out of the reach of children', and 'To be used as directed by your physician'. It also specifies storage conditions: 'Store in a dry place at a temperature not exceeding 25°C'. A copyright notice for 2022 GSK is present. At the bottom, it says 'Made by: BORA PHARMACEUTICAL SERVICES INC.'. On the right side, there is a barcode with the number '8 044000 011880'.

Seroxat CR
paroxetine hydrochloride
controlled release tablets

Each controlled release tablet contains paroxetine hydrochloride equivalent to 12.5mg paroxetine

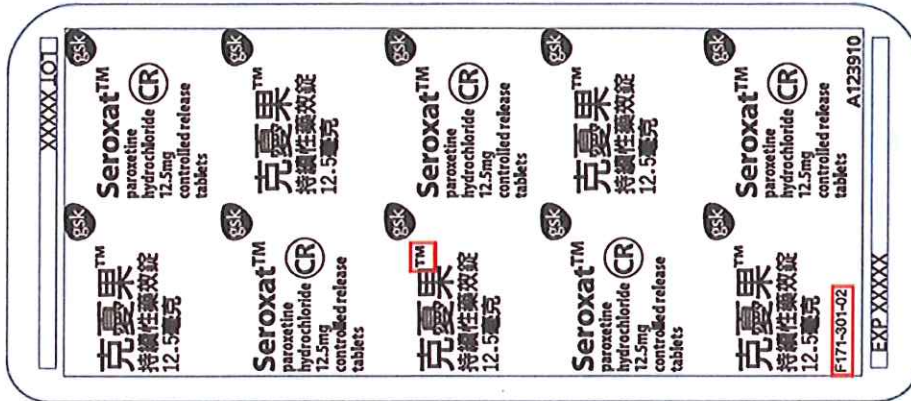
For oral use
Keep out of the reach of children
To be used as directed by your physician
Store in a dry place at a temperature not exceeding 25°C
Trade marks are owned by or licensed to the GSK group of companies.
©2022 GSK group of companies or its licensor.

Made by:
BORA PHARMACEUTICAL SERVICES INC.

8 044000 011880

標籤

變更前:



變更後:



仿單

變更前:

製造廠: Bora Pharmaceutical Services Inc.
廠址: 7333 Mississauga Road, Mississauga, Ontario, Canada, L5N 6L4
藥商: 荷商葛蘭素史克藥廠股份有限公司台灣分公司
地址: 台北市忠孝西路一段66號24樓

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變更後:

製造廠: Bora Pharmaceutical Services Inc.

廠址: 7333 Mississauga Road, Mississauga, Ontario, Canada, L5N 6L4

藥商: 荷商葛蘭素史克藥廠股份有限公司台灣分公司

地址: 台北市忠孝西路一段66號23樓

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三、因應衛福部111年3月16日衛授食字第1111402200號公告及總部通知更新其安全資訊(GDS version 48)，詳細變更內容請參閱仿單追蹤修訂版本。

四、敬請 貴單位協助轉知該產品之變更事宜，懇請繼續給予本公司支持為禱。

荷商葛蘭素史克藥廠股份有限公司台灣分公司

負責人：余慧明

