Safeguarding public health

RECIBIDO 10 ABR. 2013

Mr Frederik Peter Koopmans
HETERO EUROPE SL
VILADECANS BUSINESS PARK EDIFICIO BRASIL
CATALUNYA 83-85
VILADECANS
E-08440
SPAIN

19/03/2013

Dear Mr Koopmans,

GRANT / RENEWAL OF MARKETING AUTHORISATION

Our Reference:	PL 37222/0013 - 0001
Your Reference:	37222
Product:	Letrozole 2.5 mg Film-coated tablets
Type of Procedure:	Decentralised
Submission Type:	Initial
Submission Category:	Abridged
EU Procedure Number (if applicable):	NO/H/0227/001/DC

The Licensing Authority agrees to the grant or renewal of the marketing authorisation for the above submission on the basis of the data provided. This includes any replacement and amendment of the original dossier.

In line with Article 23a of Directive 2001/83/EC as amended, the Marketing Authorisation Holder should submit notification of the actual date of marketing of the product to the Competent Authority.
This notification should be provided by email to the following address: sunsetclause@mhra.gsi.gov.uk.

The formal documents are enclosed. These constitute evidence of authorisation. If you consider them to contain information that is incorrect or not in accordance with the dossier, please return immediately indicating any errors.

All Marketing Authorisations are subject to standard provisions contained in current medicines regulations full details of which are published on the MHRA website:

http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Informationforlicenceapplicants/Provisionstowhichthemarketingauthorisationisgranted/index.htm

Yours sincerely,

Keely Kennedy

The Medicines for Human Use (Marketing Authorisations etc.) Regulations, SI 1994/3144, as amended.

GRANT / RENEWAL OF MARKETING AUTHORISATION

Product: PL 37222/0013 – 0001 Letrozole 2.5 mg Film-coated tablets
Submission Type: Initial

Granted to: HETERO EUROPE SL
VILADECANS BUSINESS PARK EDIFICIO BRASIL
CATALUNYA 83-85
VILADECANS
E-08440
SPAIN

This Marketing Authorisation, under the above reference number is hereby granted / renewed in respect of the product named above. The Summary of Product Characteristics of the product is set out in the attached document.

The application is subject to the further provisions set out or referred to in the above Regulations.

This Marketing Authorisation, as now granted / renewed, unless previously revoked, will continue in force until the expiry date (if applicable) given below.

Grant Date: 19/03/2013

Date of Expiry: 20/02/2018

Keely Kennedy
A person authorised to sign on behalf of the Secretary of State for Health

衛生福利部藥品許可證

衛部藥輸字第 026313 號

簽審文件號碼：DHA05202631300

中文名稱：萊特汝膜衣錠 2.5 毫克

英文名稱：LETERO Film Coating Tablet 2.5mg

類　　別：本藥須由醫師處方使用

劑　　型：膜衣錠

藥商名稱：德強企業有限公司

製造廠名稱：HETERO LABS LIMITED

包裝種類：2-1000 錠鋁箔盒裝

製造廠地址：UNIT-VI, SURVEY NO.410&411, APIIC FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL,MAHABOOB NAGAR DISTRICT. 509 301, ANDHRA PRADESH, INDIA

處　　方：

Each F.C. Tablet contains:

Letrozole.....2.5 mg

適 應 症：詳如後

前項藥品經本部審核與藥事法之規定相符應發給許可證以資證明

衛 生 福 利 部

部長 邱文達

發證日期 103 年 05 月 12 日

有效日期 108 年 05 月 12 日

核准展延至	年 月 日	年 月 日	年 月 日	年 月 日
文號				

ME 000612

其他	變更事項	核准文號	核准日期	變更事項	核准文號	核准日期

適應症：

接受抗動情激素治療失敗的自然或人工停經後之末期乳癌病人之治療。
停經後之局部晚期或轉移性乳癌婦女患者之第一線治療用藥。
荷爾蒙接受器呈陽性及 LN METASTASIS POSITIVE 之乳癌病人作為 TAMOXIFEN 輔助療法之後的延伸治療。
停經後荷爾蒙接受器呈陽性反應的初期乳癌病人之輔助治療。

09003057

No. 055134

FORM 7
表格 7

[reg. 36(5).]
〔第36(5)條〕

PHARMACY AND POISONS ORDINANCE
藥劑業及毒藥條例

(Chapter 138)
(第138章)

CERTIFICATE OF DRUG/PRODUCT REGISTRATION
藥品/製品註冊證明書

It is hereby certified that I & C (HONG KONG) LIMITED
現證明 FLAT/RM E, 28/F
CNT TOWER 338 HENNESSY ROAD WAN CHAI HK
(Name and Address)
(姓名或名稱及地址)

has been issued with a permit No. HK— 61538 authorizing
已獲發編號為 的許可證，准許將

LETROZOLE TABLETS 2.5MG (HETERO)
(Name of drug/product) to be marketed for use
(藥品/製品名稱)在市場出售以供

within Hong Kong.
在香港使用。

2. This certificate will be valid until 28 October, 2017 and thereafter
本證明書的有效期至 年 月 日止，

for periods of five years at a time on renewal and subject to the payment of the registration fee.
之後在註冊費繳付後，每次續期的有效期為5年。

3. No change in the formulation and commercial presentation of this product shall be made
在註冊有效期內，未經藥劑業及毒藥管理局批准，

during the effectivity of this registration without the approval of the Pharmacy and Poisons Board.
不得更改該製品的合成方式及商業外觀。

HONG KONG.
香港

29/10/2012 (Date)
(日期)

(K.W. LAU) (代行)
for *Pharmacy and Poisons Board*
藥劑業及毒藥管理局

CLASSIFICATION ON DATE OF ISSUE:
PART I, FIRST & THIRD SCHEDULE POISON

The Drug Permit License issued by the Food and Drug Administration, Ministry of Health and Welfare of the Republic of China

Drug Permit License Number: 026313

Application Number: DHA05202631300

Product Name in Chinese:	萊特汝膜衣錠 2.5 毫克		
Product Name in English:	LETEOR Film Coating Tablet 2.5 mg		
Drug Classification:	A prescription drug that requires a physician's medical prescription to be dispensed.	Name of Pharmaceutical Company:	De Ciang Enterprises Ltd.
Dosage Form:	Film-coated tablets	Name of Product Manufacturer: (Stamp)	HETERO LABS LIMITED UNIT-VI, SURVEY NO. 410% 411 APIIC FORMULATION SEZ, POLEPALLY VILLAGE, JADCHERLA MANDAL, MAHABOOB NAGAR DISTRICT. 509 301, ANDHRA PRADESH, INDIA (Stamp)
Type of Packaging:	2-1000 tablets in a retort pouch		

Active Ingredients:
Each F.C. Tablet contains:
Letrozole……2.5 mg

Indications: Please see the details below.

The permit license is hereby granted in respect of the product named above, which has been assessed by the Ministry of Health and Welfare and found to

conform to the regulations of the Pharmaceutical Affairs Act.

Ministry of Health and Welfare of the Republic of China
Minister Chiu Wen-ta (Stamp)
Permit License Grant Date: May 12th, 2014
Valid Until: May 12th, 2019

Approved Time	Year Month Date	Year Date	Month	Year Date	Month	Year Date	Month

Extension until:

Document Number (Stamp)

Others	Amendments	Approval Number	Approval Date	Amendments	Approval Number	Approval Date

Indications:

The product is used to treat advanced breast cancer in women who have experienced natural or induced menopause after treatment failure with anti-estrogens.

This product is a frontline drug to treat postmenopausal women with locally advanced breast cancer or metastatic breast cancer.

This product is used as an extensional treatment for hormone receptor-positive and lm metastasis positive breast cancer patients following the supplementary tamoxifen therapy.

This product is used as a supplementary treatment for postmenopausal patients with early stage hormone receptor-positive breast cancer.

ME 000612