副　本

中华人民共和国
The People's Republic of China

进口药品注册证
IMPORTED DRUG LICENSE

注册证号：H20120532
LICENSE NO.

根据《中华人民共和国药品管理法》和
In accordance with **The Drug Administration Law of P.R.of China** and **The Provisions**
《药品注册管理办法》的规定，兹批准下述
for Drug Registration, the following drug produced by the following company has been
公司的下述药品注册。允许进口使用。
approved and registered.The importation has been authorized thereby.

公司名称：Scora S.A.
Company

地　　址：Rue de l'Usine 62132 Caffiers　　国　家：法国
Address　　Country　France

药品名称：碳酸钙　　商品名：
Generic Name　Calcium Carbonate　　Trade Name

主要成份：碳酸钙
Active Ingredients　Calcium Carbonate

剂　　型：原料药　　规　格：
Dosage Form　　Strength

包装规格：20kg/包，1000kg/包　　药品有效期：24个月
Package Size　　Shelf life

生 产 厂：Scora S.A.
Manufacturer

地　　址：Rue de l'Usine 62132 Caffiers　　国　家：法国
Address　　Country　France

备　　注：1. 本证有效期至 2017年 12月 13日
Remarks　Valid Until　Dec. 13, 2017

2. 注册标准：进口药品注册标准JX20120085。
Specifications

3. 原H20020456号《进口药品注册证》注销。

国家食品药品监督管理局
State Food and Drug Administration

2012年 12月 13日
Dec. 13, 2012

FOOD AND DRUG ADMINISTRATION 国家食品药品监督管理局 进口药品注册专用章 IMPORT DRUG REGISTRATION

NO. 1100848

注 意 事 项

POINTS OF ATTENTION

1. 本证是国家食品药品监督管理局核发的允许所列品种进口和销售使用的批准证明文件，分为“正本”和“副本”。未取得本证的品种不得进口、销售使用。在办理进口备案时，必须出示本证“正本”或“副本”原件。

   This license, both in form of "*Reserved Copy*" and "*Duplicate Copy*", is the legal document issued by ***State Food and Drug Administration of People's Republic of China*** indicating the authorization granted to a given drug specified therein for its importation, marketing and sales in China. No importation, marketing and sales of any pharmaceuticals are permitted without this license. When submitting a post registration archive of approved drugs to coastal Food and Drug Administration, the original license should be presented.

2. 进口的药品必须使用中文包装，注明本证规定的“药品名称”、“注册证号”以及所列“公司”和“生产厂”名称、地址等。包装、标签内容与本证不一致的，不得进口。“注册证号”有变化的，必须注明新注册证号，原注册证号废止。

   The package should be printed in Chinese and indicated clearly the generic name of the approved drug, the license number, and the name and address of the "company" and / or "manufacturer". No importation is permitted, in case of any divergence from the specified in the license. The new license number should be used if the number is changed, whereas the old one becoming invalid simultaneously.

3. 本证所列“公司”指对本注册品种拥有上市权的公司，并对该品种质量负法律责任；“生产厂”指本注册品种的具体生产工厂。

   The "company" hereby refers to the marketing authorization holder, and holds legal responsibility for the quality assurance; whereas the "manufacture" refers to the specific plant, in which the pharmaceutics is produced.

4. 本证注明的生产厂分为二类：（1）该厂完成本注册品种从制剂到包装全过程；（2）该厂只负责本注册品种制剂生产，不负责包装；该注册品种包装厂的名称、地址将在“备注”中注明。

   The "manufacturer" hereby falls into two categories: (1) manufacturing, packaging and labeling the dosage form; (2)manufacturing the dosage form only. In this case, the name and address of the packaging and labeling plant will be indicated under the item of "remarks".

5. 注册证的使用不得违反中国药品管理法律和法规。

   Any violation of laws and regulations of China governing its drug administration when using the license is forbidden.

6. 本证自签发之日起5年有效，必须在有效期届满前6个月提出再注册申请，经审核批准的，予以再注册。

   The license is valid for five years form issuing date. A renewal application must be submitted 6 months prior to its expiry. A new license will be given once the application is approved.

7. 本证所载项目内容有变化的，应及时向我局提出药品补充申请。经批准后方可进口。

   Drug Supplementary application should be timely submitted, if there is any changes in contents specified in the license. The proposed change is seen valid after its approval.

8. 本证请妥善保管，遗失或损坏的不予补发。

   The license should be well preserved and no re-issue will be made in case of loss and/or damage.