CERTIFIED HPRA

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Certificate of a Pharmaceutical Product

This certificate conforms to the format recommended by the World Health Organisation

Exporting (certifying) country: **Ireland**

Importing (requesting) country: **Chile**

1. Name and dosage form of product:

Zeldox cápsulas 60 mg (Nuevo Sitio) known in Ireland as Geodon 60mg capsules, hard.

1.1 Active ingredient(s) and amount(s) per unit dose:

Ziprasidone hydrochloride monohydrate INN **60 mg**

For complete qualitative composition including excipients see attached.

1.2 Is this product licensed to be placed on the market for use in the exporting country?
Yes

1.3 Is this product actually on the market in the exporting country?
No

If the answer to 1.2 is 'yes', continue with section 2.A and omit section 2B;
If the answer to 1.2 is 'no', omit section 2A and continue with section 2B

2A.1 Number of product licence and date of issue:

PA0822/214/003 issued 8th March 2002

2A.2 Product licence holder (name and address):

Pfizer Healthcare Ireland,
9 Riverwalk, National Digital Park,
Citywest Business Campus,
Dublin 24,
Ireland.

2A.3 Status of product licence holder: a, b or c: **c**

A.3.1 For categories b and c, state the name and address of the manufacturer producing the dosage form:

Pfizer Ireland Pharmaceuticals,
Little Connell,
Newbridge,
Co. Kildare,
Ireland.

2A.4 Is the summary Basis of Approval appended?
No

2A5. Is attached, officially approved product information complete and consonant with the licence?
Yes

2A.6 Applicant for certificate, if different from licence holder (name and address):

FMD KL Europe LLC,
3a Hakob Hakobyan Str.,
Yerevan, 0031,
Republic of Armenia.

2B.1 Applicant for certificate (name and address):

2B.2 Status of applicant:

2B.2.1 For categories b and c, state the name and address of the manufacturer producing the dosage form:

2B.3 Why is marketing authorisation lacking?

2B.4 Remarks:

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
Yes

3.1 Periodicity of routine inspection (years):
Every 3 years

3.2 Has the manufacture of this type of dosage form been inspected?
Yes

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organisation?
Yes

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or official HPRA use only:

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?
Yes

Address of certifying authority:
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Ireland

Telephone no: 01-676-4971 **Fax no:** 01-676-4061

Name of authorised person:

Patrick Keating
A person authorised in that behalf by the said Authority
Compliance Department
6th December 2018

N.B. The information contained in the certificate is a valid and true reflection of the latest available information pertaining to the product authorisation available at the time of issue.

An tÚdarás Rialála Táirgí Sláinte, Teach Kevin O'Malley, Ionad Phort an Iarla, Baile Átha Cliath 2, Éire
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APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Country: Pays/País:	**IRELAND**
This public document Le présent acte public / El presente documento público	
2. has been signed by a été signé par ha sido firmado por	Patrick Keating
3. acting in the capacity of agissant en qualité de quien actúa en calidad de	Health Products Regulatory Authority
4. bears the seal / stamp of est revêtu du sceau / timbre de y está revestido del sello / timbre de	N/A

Certified
Attesté / Certificado

5. at à / en	Dublin	**6. the** le / el día	03/01/2019
7. by par / por	Department of Foreign Affairs and Trade		
8. No sous no bajo el número	4150332019		
9. Seal / stamp: Sceau / timbre Sello / timbre	**10. Signature:** Signature: Firma:		

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