

Boehringer Ingelheim Ltda. · Santiago · Chile

**Boehringer Ingelheim Ltda.**  
Dirección Técnica

6 de octubre de 2016

**REF: Certificación FDA**

**Producto: Pradaxa Cápsulas 110 mg  
Pradaxa Cápsulas 150 mg**

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Estimados:


Por medio de la presente informamos a Ud, que los productos **Pradaxa Cápsulas 110 mg y Pradaxa Cápsulas 150 mg** registrados en Chile bajo los N° F-17448/14 y F-18648/16 respectivamente, fue aprobado por la FDA el 01 de agosto 2014, autorización número (NDA) 022512. Se adjunta documento obtenido de la base de datos de la FDA.


General del Canto # 421  
Piso 6 / Providencia  
Santiago/Chile  
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Sin otro en particular, le saluda atte,  
BOEHRINGER INGELHEIM LTDA.



**Q.F. Claudia Mejías G.**  
**Directora Técnica**

 U.S. Department of Health & Human Services




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Drug Details

Drug Name(s)	PRADAXA
FDA Application No.	(NDA) 022512
Active Ingredient(s)	DABIGATRAN ETEXILATE MESYLATE
Company	BOEHRINGER INGELHEIM
Original Approval or Tentative Approval Date	October 19, 2010
Chemical Type	1 New molecular entity (NME)
Review Classification	P Priority review drug

- There are no Therapeutic Equivalents
- Approval History, Letters, Reviews, and Related Documents
- Medication Guide

- Label Information
- Other Important Information from FDA

Products on Application (NDA) #022512

Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
PRADAXA	DABIGATRAN ETEXILATE MESYLATE	EQ 75MG BASE	CAPSULE;ORAL	Prescription	No	None
PRADAXA	DABIGATRAN ETEXILATE MESYLATE	EQ 150MG BASE	CAPSULE;ORAL	Prescription	Yes	None
PRADAXA	DABIGATRAN ETEXILATE MESYLATE	EQ 110MG BASE	CAPSULE;ORAL	Prescription	No	None

Back to Top

 | 

Back to Previous Page


 | 

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U.S. Food and Drug Administration

10903 New Hampshire Avenue








Combination Products

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