

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  
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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    |

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U.S. Food and Drug Administration

10903 New Hampshire Avenue

Combination Products  
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 U.S. Department of Health & Human Services

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