

Boehringer Ingelheim Ltda. · Santiago · Chile

Boehringer Ingelheim Ltda.
Dirección Técnica

6 de octubre de 2016

REF: Certificación FDA

**Producto: Sifrol Comprimidos 0,25 mg
Sifrol Comprimidos 1 mg**

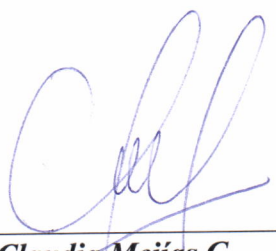
Estimados:

Por medio de la presente informamos a Ud, que los productos **Sifrol Comprimidos 0,25 mg y Sifrol Comprimidos 1 mg** registrados en Chile bajo los N° F-1783/14 y F-1782/14 respectivamente, fue aprobado por la FDA el 01 de julio 1997, autorización número (NDA) 020667. Se adjunta documento obtenido de la base de datos de la FDA.

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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)	MIRAPEX
FDA Application No.	(NDA) 020667
Active Ingredient(s)	PRAMIPEXOLE DIHYDROCHLORIDE
Company	BOEHRINGER INGELHEIM
Original Approval or Tentative Approval Date	July 1, 1997
Chemical Type	1 New molecular entity (NME)
Review Classification	S Standard review drug

- Therapeutic Equivalents
- Approval History, Letters, Reviews, and Related Documents

- Label Information
- Other Important Information from FDA

Products on Application (NDA) #020667

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

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
MIRAPEX	PRAMIPEXOLE DIHYDROCHLORIDE	0.125MG	TABLET;ORAL	Prescription	No	AB
MIRAPEX	PRAMIPEXOLE DIHYDROCHLORIDE	0.25MG	TABLET;ORAL	Prescription	Yes	AB
MIRAPEX	PRAMIPEXOLE DIHYDROCHLORIDE	1MG	TABLET;ORAL	Prescription	No	AB
MIRAPEX	PRAMIPEXOLE DIHYDROCHLORIDE	1.25MG	TABLET;ORAL	Discontinued	No	None
MIRAPEX	PRAMIPEXOLE DIHYDROCHLORIDE	1.5MG	TABLET;ORAL	Prescription	No	AB
MIRAPEX	PRAMIPEXOLE DIHYDROCHLORIDE	0.5MG	TABLET;ORAL	Prescription	No	AB
MIRAPEX	PRAMIPEXOLE DIHYDROCHLORIDE	0.75MG	TABLET;ORAL	Prescription	No	AB

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MIRAPEX	PRAMIPEXOLE DIHYDROCHLORIDE	1MG	TABLET;ORAL	Prescription	No	AB
MIRAPEX	PRAMIPEXOLE DIHYDROCHLORIDE	1.25MG	TABLET;ORAL	Discontinued	No	None
MIRAPEX	PRAMIPEXOLE DIHYDROCHLORIDE	1.5MG	TABLET;ORAL	Prescription	No	AB
MIRAPEX	PRAMIPEXOLE DIHYDROCHLORIDE	0.5MG	TABLET;ORAL	Prescription	No	AB
MIRAPEX	PRAMIPEXOLE DIHYDROCHLORIDE	0.75MG	TABLET;ORAL	Prescription	No	AB

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