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Boehringer Ingelheim Ltda.
Dirección Técnica

6 de octubre de 2016

REF: Certificación FDA
Producto: Sifrol Comprimidos 0,25 mg
Sifrol Comprimidos 1 mg

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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.

Sin otro en particular, le saluda atte,
BOEHRINGER INGELHEIM LTDA.

Q.F. Claudia Mejías G.
Directora Técnica

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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	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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