

Isotretinoin iPLEDGE shared system
RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Current application holders of the shared system REMS

Product name	Application number	Application holder
Absorica	NDA 021951	Ranbaxy Laboratories Inc.
Zenatane	ANDA 202099	Dr. Reddy's Laboratories Ltd. US Agent: Dr. Reddy's Laboratories Inc.
Sotret	ANDA 076503	Ranbaxy Laboratories Inc.
Myorisan	ANDA 076485	Douglas Pharmaceuticals America Ltd. US Agent: VersaPharm Inc.
Claravis	ANDA 076356	Teva Pharmaceuticals USA
Claravis	ANDA 076135	Teva Pharmaceuticals USA
Sotret	ANDA 076041	Ranbaxy Laboratories Inc.
Amnesteem	ANDA 075945	Mylan Pharmaceuticals Inc.

Number of total products= 8