

**Rosiglitazone shared system**  
**RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

Current application holders of the shared system REMS

<b>Product name</b>	<b>Application number</b>	<b>Application holder</b>
Avandia	NDA 021071	SmithKline Beecham (Cork) Ltd d/b/a GlaxoSmithKline
Avandamet	NDA 021410	SmithKline Beecham (Cork) Ltd d/b/a GlaxoSmithKline
Avandaryl	NDA 021700	SmithKline Beecham (Cork) Ltd d/b/a GlaxoSmithKline
rosiglitazone maleate	ANDA 076747	Teva Pharmaceuticals USA, Inc.
rosiglitazone maleate and metformin hydrochloride	ANDA 077337	Teva Pharmaceuticals USA, Inc.

Number of total products= 5