

Safety Review

The side effects of Narrowband UVB phototherapy are typically rare, mild, and topical; the most common are erythema and dry skin. The therapy is safe for use by children, the elderly, and patients who are pregnant, or nursing. It can be used with patients who are HIV+, or who have other conditions such as diabetes*.

The safety profile of the biologic drugs frequently used for the treatment of skin disease is not as favorable. The following chart is a compilation of statistics from the FDA on adverse events and deaths attributed to the use of the more common biologic agents.

Chart A: Number of Adverse Events where the Primary Suspect was a Drug

Drug Family	2006-2009 Data	2010-2012 Data	2013-2015 Data	2016	2017	2018	2019	2020	Total Reactions
Oxsoalalen	1	1	1	2	4	3	3	2	17
Skyrizi®							279	1,818	2,097
Tremfya®					31	354	771	994	2,150
Taltz™				47	411	521	741	652	2,372
Otezla®			1,875	3,002	3,721	3,138	3,069	3,439	18,244
Simponi®				4,429	3,300	3,170	2,999	4,926	18,824
Protopic®	300	131	193	2,480	3,276	5,784	4,736	5,873	22,773
Cimzia®				5,009	4,490	4,597	7,676	6,394	28,166
Cosentyx®			238	1,614	3,889	7,581	8,851	11,711	33,884
Stelara®	37	2,791	3,663	3,280	3,758	5,258	5,417	11,278	35,482
Xeljanz®				3,504	4,891	7,102	10,744	12,307	38,548
Orencia®				5,190	6,458	11,229	11,484	9,212	43,573
Methotrexate	1,077	1,255	2,999	5,071	8,090	14,766	19,325	18,274	70,857
Remicade®	16,630	24,073	15,232	8,671	6,148	6,232	8,006	14,045	99,037
Enbrel®	9,102	17,545	35,418	19,404	18,357	15,285	10,690	7,864	133,665
Humira®	8,944	20,097	26,246	27,129	32,014	35,720	36,820	32,444	219,414
Grand Total Per Year	36,091	65,893	85,865	88,832	98,838	120,740	131,611	141,233	769,103

Chart B: Number of Deaths where the Primary Suspect was a Drug

Drug Family	2006-2009 Data	2010-2012 Data	2013-2015 Data	2016	2017	2018	2019	2020	Total Deaths
Oxsoalalen					1			2	3
Skyrizi®							13	123	136
Tremfya®					3	24	25	44	96
Taltz™				4	19	31	54	68	176
Simponi®				97	88	104	101	157	547
Cimzia®				135	151	150	191	235	862
Cosentyx®			19	82	155	232	314	467	1,269
Otezla®			56	169	203	257	271	205	1,161
Stelara®	2	236	260	117	166	150	147	269	1,347
Xeljanz®				210	318	451	676	653	2,308
Orencia®				286	378	564	492	464	2,184
Protopic®	27	12	7	314	378	709	453	576	2,476
Methotrexate	443	398	500	333	588	817	941	994	5,014
Remicade®	2,932	1,999	838	230	205	209	246	337	6,996
Enbrel®	1,409	1,464	2,915	809	894	841	498	531	9,361
Humira®	2,289	3,576	3,512	1,571	1,876	2,106	1,938	1,879	18,747
Grand Total Per Year	7,102	7,685	8,107	4,357	5,423	6,645	6,360	7,004	52,683

Data compiled using MedWatch statistics available at FDA.gov – Skyrizi® (risankizumab-rzaa injection) and Humira® (adalimumab) are registered trademarks of AbbVie Inc., Tremfya® (guselkumab) is a registered trademark of Johnson & Johnson, Taltz™ (ixekizumab) is a registered trademark of Lilly, Simponi® (golimumab), Stelara® (ustekinumab) and Remicade® (infliximab) are registered trademarks of Janssen Biotech, Cimzia® (certolizumab pegol) is a registered trademark of UCB Group, Cosentyx® (secukinumab) is a registered trademark of Novartis, Otezla® (apremilast) is a registered trademark of Amgen Inc., Xeljanz® (tofacitinib) is a registered trademark of Pfizer, Orencia® (Abatacept) is a registered trademark of Bristol Myers Squibb, Enbrel® (Etanercept) is a registered trademark of Amgen, Inc./Wyeth Pharmaceuticals, ProTopic® (tacrolimus) is a registered trademark of Astellas Pharma.

*Archier, E., Devaux, S., Castela, E. et al. Efficacy of psoralen UV-A therapy vs. narrowband UV-B therapy in chronic plaque psoriasis: a systematic literature review. J Eur Acad Dermatol Venereol. 2012; 26: 11-2

