

Retreatment with telaprevir combination therapy in hepatitis C patients with well-characterized prior treatment response.

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Table 3. Adverse Events Leading to Discontinuation and Most Common Adverse Events Reported According to Treatment Group

	T12PR24	T12PR48	Unassigned*	Total
n (%)	N = 81	N = 34	N = 2	N = 117
Adverse events leading to discontinuation**	5 (6)	3 (9)	2 (100)	10 (9)
Rash events‡	4 (5)	1 (3)	1 (50)	6 (5)
Pruritus	1 (1)	0 (0)	1 (50)	2 (2)
Pyrexia	1 (1)	1 (3)	0 (0)	2 (2)
Anemia	2 (2)	0 (0)	0 (0)	2 (2)
Adverse events occurring in >10% of patients, n (%)				
Severe adverse event	12 (15)	7 (21)	1 (50)	20 (17)
General disorder				
Fatigue	30 (37)	21 (62)	1 (50)	52 (44)
Influenza-like illness	17 (21)	10 (29)	1 (50)	28 (24)
Pyrexia	16 (20)	6 (18)	0 (0)	22 (19)
Chills	11 (14)	4 (12)	0 (0)	15 (13)
Asthenia	9 (11)	3 (9)	0 (0)	12 (10)
Gastrointestinal disorder				
Nausea	20 (25)	11 (32)	1 (50)	32 (27)
Diarrhea	19 (24)	6 (18)	0 (0)	25 (21)
Hemorrhoids	9 (11)	4 (12)	0 (0)	13 (11)
Skin and subcutaneous disorders				
Pruritus	34 (42)	9 (26)	2 (100)	45 (38)
Rash†	23 (28)	13 (38)	1 (50)	37 (32)
Dry skin	10 (12)	5 (15)	0 (0)	15 (13)
Nervous system disorders				
Headache	23 (28)	14 (41)	0 (0)	37 (32)
Psychiatric disorders				
Insomnia	14 (17)	7 (21)	1 (50)	22 (19)
Depression	9 (11)	4 (12)	0 (0)	13 (11)
Musculoskeletal disorders				
Myalgia	10 (12)	5 (15)	0 (0)	15 (13)
Arthralgia	11 (14)	2 (6)	0 (0)	13 (11)
Respiratory disorders				
Cough	9 (11)	4 (12)	2 (100)	15 (13)
Blood and lymphatic disorders				
Anemia	22 (27)	7 (21)	0 (0)	29 (25)

*Unassigned patients discontinued treatment prior to week 12 assignment of treatment duration.

**Adverse events leading to discontinuation in ≥ 2 patients.

‡This category includes all patients experiencing rash events as assessed with the use of a group of related terms to identify all dermatologic events. All treatment discontinuations due to rash happened during telaprevir phase.

†Using a variety of descriptive terms to identify all dermatologic events, rash events occurred in 44%, 53%, 100%, and 48% of T12PR24, T12PR48, Unassigned, and Total patients, respectively.