

Boceprevir & Telaprevir Treatment Tables

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Drug Administration

	Boceprevir	Telaprevir
Dose	800 mg q 8+/-1 h (6-14-22 h)	750 mg q 8+/-1 h (6-14-22 h)
Strength	200 mg tab	375 mg tab
Length	24-44 wks	12 wks
Administration	PO with food	PO with fatty (> 20gm) food
Missed dose	If < 6 h post-time: take and keep schedule. If > 6 h post-time: skip and keep schedule.	If < 4 h post-time: take and keep schedule. If > 4 h post-time: skip and keep schedule
Co-therapy	Can only be given with both Peg-IFN and RBV. Discontinue if any of them is discontinued.	Can only be given with both Peg-IFN and RBV. Discontinue if any of them is discontinued.
Futility: D/C if	HCV-RNA \geq 100 IU/mL @ wk 12 HCV-RNA \geq 9.3 IU/mL @ wk 24	HCV-RNA > 1000 IU/mL @ wk 4 or 12 HCV-RNA > 10 IU/mL @ wk 24

CONTRAINDICATIONS

Class	Boceprevir	Telaprevir	Effect
Alfa1 adrenoreceptor antagonist	Alfuzosin	Alfuzosin	Hypotension, arrhythmia
Anticonvulsant	Carbamazepine, phenobarb, phenytoin		Viral escape
Anti-TB	Rifampin	Rifampin	Viral escape
Ergot derivate	Dihydroergotamine, ergonovine, ergotamine, methylergonovine	Dihydroergotamine, ergonovine, ergotamine, methylergonovine	Vasospasm, ischemia
GI Motility	Cisapride	Cisapride	Arrhythmia
Herbal	St John's Wort	St John's Wort	Viral escape
HMG-CoA Reduct inh	Lovastatin, simvastatin	Lovastatin, simvastatin, atorvastatin	Myopathy, rhabdomyolysis
Contraceptive	Drosperinone		Hyperkalemia
PDE5 enz inhibitor	Sildenafil, tadalafil.	Sildenafil, tadalafil.	Hypotension, syncope, priapism
Neuroleptic	Pimozide	Pimozide	Arrhythmia
Sedative	Midazolam, triazolam (oral)	Midazolam, triazolam (oral)	Oversedation, Resp depression

Boceprevir FDA Algorithms Genotype-1 Naive Response-Guided Therapy by HCV-RNA drop

	TW-0	TW-4	TW-8	TW-12	TW-24	TW-28	TW-36	TW-48	SVR
	Start P/R	Add B PRB	PRB	PRB *	PRB **	PRB	PRB	(PRB)	
NAÏVE All				< 100	< 9.3				63-66
NAÏVE (56%)		drop > 0.5 log	< 9.3	< 9.3	< 9.3	EOT			88
NAIVE		drop > 0.5 log	> 9.3	< 100	< 9.3		D/C B	PR EOT	75
Cirrhosis NAIVE				< 100	< 9.3			EOT	42
Af Am NAÏVE				< 100	< 9.3			by RGT/ or EOT	42-53
Any		drop < 0.5 log		< 100	< 9.3			EOT	30

* If HCV-RNA \geq 100 IU/mL at week 12: Discontinue therapy
 ** If HCV-RNA \geq 9.3 IU/mL at week 24: Discontinue therapy

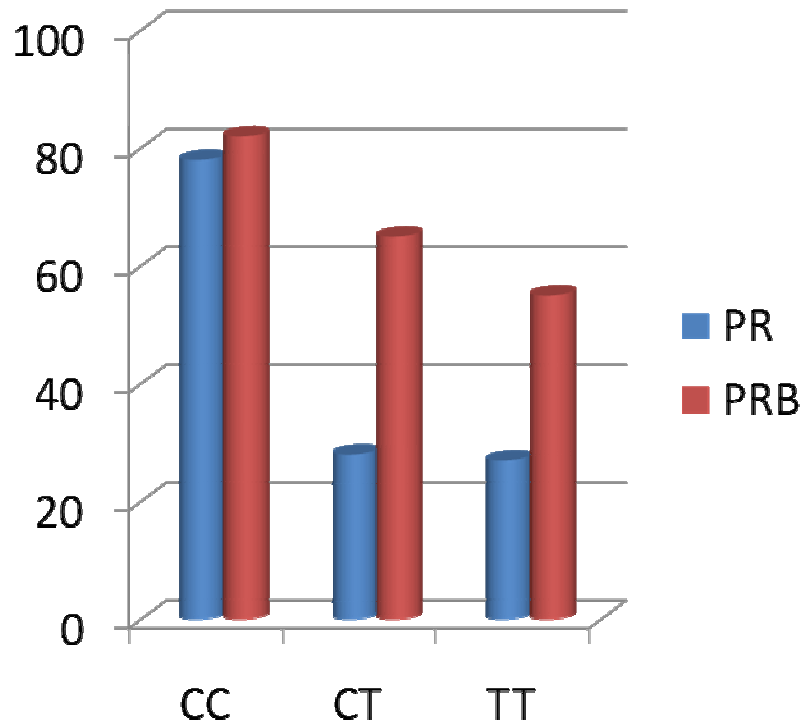
Boceprevir FDA Algorithms Genotype-1 Experienced Response-Guided Therapy by HCV-RNA drop

	TW-0	TW-4	TW-8	TW-12	TW-24	TW-28	TW-36	TW-48	SVR
	Start P/R	Add B PRB	PRB	PRB *	PRB **	PRB	PRB	(PRB)	
Past pEVR or Relapser (48%)		drop > 0.5 log	< 9.3	< 9.3	< 9.3		EOT		88
Past pEVR or Relapser		drop > 0.5 log	> 9.3	< 100	< 9.3		D/C B	PR EOT	79
Cirrhosis pEVR				< 100	< 9.3			EOT	35
Any		drop < 0.5 log		< 100	< 9.3			EOT	30
Past P/R wk12 drop < 2 log				< 100	< 9.3			EOT	?

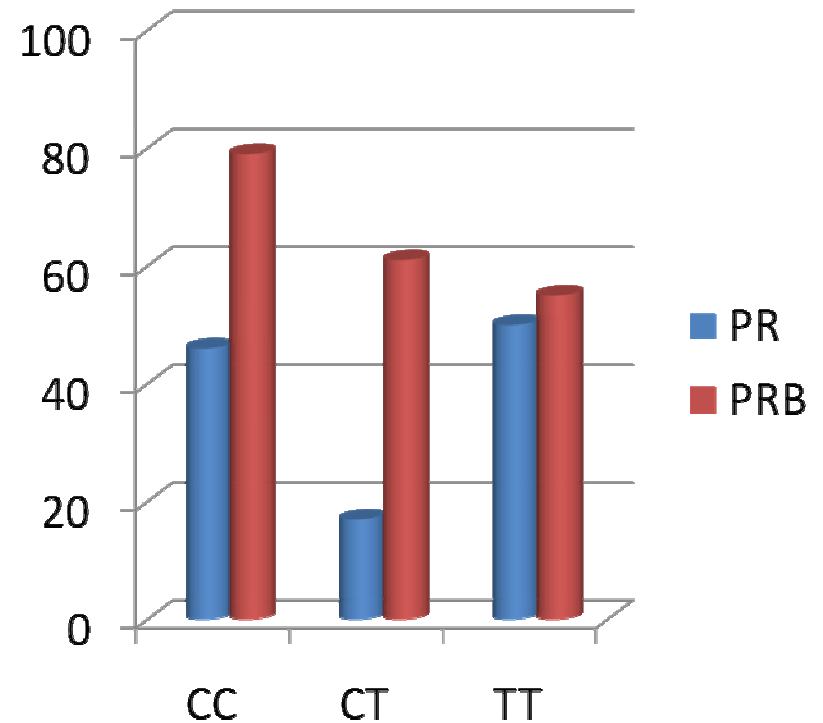
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Effect of IL-28B rs12979860 Genotype in SVR with Boceprevir + P/R in G-1

NAIVE



PREVIOUS TREATMENT FAILURE



Telaprevir FDA Algorithms Genotype-1 Naive Response-Guided Therapy by HCV-RNA drop

	TW-0	TW-4	TE-12	TW-24	TW-48	SVR
	PRT	PRT *	D/C T *	PR **	(PR)	
NAÏVE (All)		< 1000	< 1000	< 10		79
NAÏVE (58%)		< 10	< 10	EOT		92
NAÏVE (42%)		10-1000	10-1000	< 10	EOT	60
NAÏVE Af Am (31%)		< 10	< 10	EOT		89
NAÏVE Af Am (69%)		10-1000	10-1000	< 10	EOT	44
NAÏVE Cirrhosis (43%)		< 10	< 10	EOT		78
NAÏVE Cirrhosis (57%)		10-1000	10-1000	< 10	EOT	33

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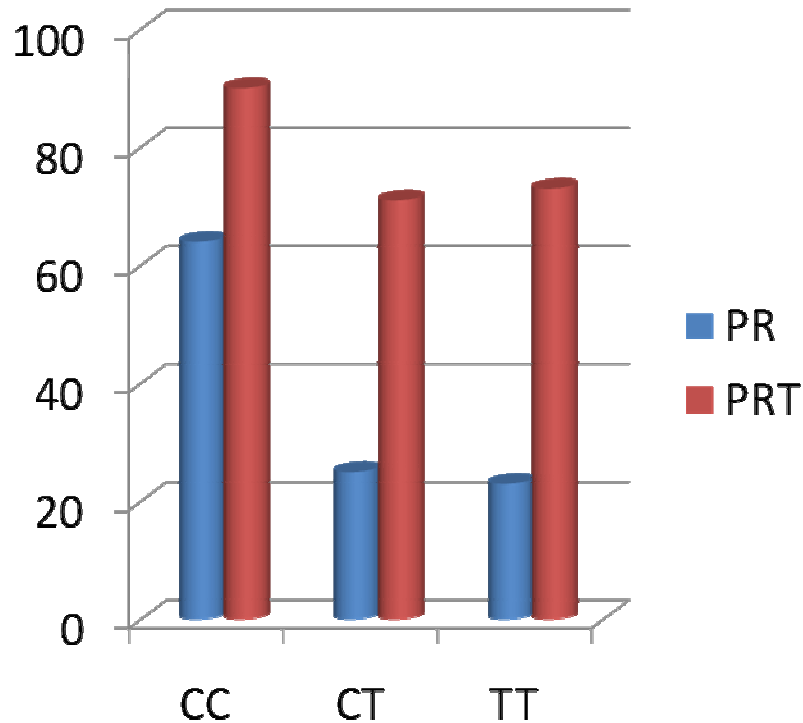
Telaprevir FDA Algorithms Genotype-1 Experienced Response-Guided Therapy by HCV-RNA drop

	TW-0	TW-4	TE-12	TW-24	TW-48	SVR
	PRT	PRT *	D/C T *	PR **	PR	
Pelapsers (All)		< 1000	< 1000	< 10	EOT	86
Relapser (76%)		< 10	< 10	< 10	EOT	95
Relapser (24%)		10-1000	10-1000	< 10	EOT	15
pEVR (All)		< 1000	< 1000	< 10	EOT	59
< 2 log w12 (All)		< 1000	< 1000	< 10	EOT	32
Relapser Cirrhosis		< 10	< 10	< 10	EOT	87
pEVR Cirrhosis		< 1000	< 1000	< 10	EOT	20
< 2 log w12 Cirrhosis		< 1000	< 1000	< 10	EOT	10

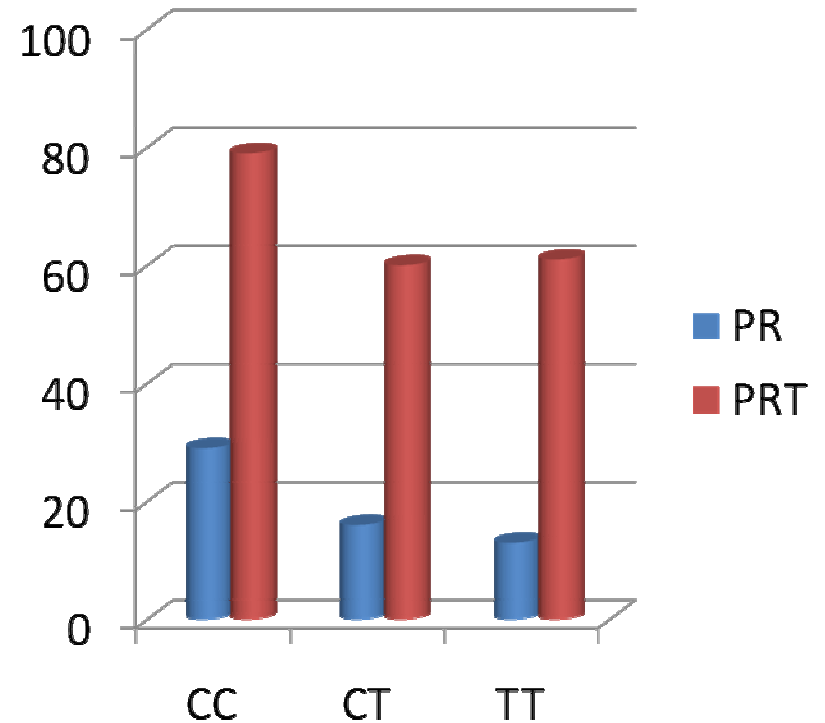
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Effect of IL-28B rs12979860 Genotype in SVR with Telaprevir + P/R in G-1

NAIVE



PREVIOUS TREATMENT FAILURE



Adverse Events (%)

Event	Boc + Peg/Riba	Tel + Peg/Riba	Peg/Riba
Rash	17	56	19-34
Fatigue	58	56	50
Anemia	50	36	17-30
Pruritus		47	28
Nausea	46	39	28-38
Chills	34		30
Diarrhea	25	26	17
Neutropenia	25	15	14
Dizziness	19		13
Vomiting	20	13	8
Hemorrhoids		12	3
Anorectal discomfort		11	3
Dysgeusia	35	10	3
Pruritus ani		6	1