



6B10A0

25mg QD 96 666 HBV 670
 ALT 11.1% 10.5%
 8.1% AST 7.2%
 5.0% 5.0% 1

	25mg (N=666) n (%)	TDF 300mg (N=336) n (%)
	74(11.1)	34(10.1)
	54(8.1)	26(7.7)
	30(4.5)	34(10.1)
	48(7.2)	29(8.6)
	33(5.0)	15(4.5)
	70(10.5)	31(9.2)
	33(5.0)	7(2.1)

96 3 ALT 3.8%
 AST 1.8% TDF 2.7% 2.7%
 14.4% 4.8% 6.2% 3.3% 4.4%
 0.3% 3.0% 0% 1~2
 3.9%
 ALT ALT 2× 10×
 1.7% TDF 3.0%
 144 96 48
 1002
 13.5% ALT 13.4% 10.1% AST 8.6%
 8.4% 7.8% 6.0%

DNA

HBV

6

ALT

HBV

Child-Pugh >9 C HBV

CrCl <50mL/min HBV

3.0% 96 14.4% 4.8% TDF 48 11.4%

HBV

HCV

HDV

HBV

HIV

HBV

HIV

HBV

HIV

-

144

3

18

65

P-

P-gp

P-gp

P-

gp

P-gp

2

2

	mg	mg	N	PK	
				90% =1	
				C _{max}	AUC
	300mg	25mg	15	0.36 0.28~0.47	0.40 0.33~0.49
	150mg	10mg	19	2.86 2.26~3.62	2.91 2.49~3.39

P-gp

P-gp

P-gp

P-gp

Ia

40mg 6

80mg 6

Ib

9 HBV

40mg

2

HS-10234-301

III

25mg QD

TDF 300mg QD

HBeAg

2:1

TDF

96

48

HBeAg

732 HBeAg 25mg TDF 300mg

486 246 TDF 34 71%

93.3% 6.4% 28.9%

HBV DNA 7.3log₁₀ IU/mL ALT 136U/L 60.7% 38.8%

HBV C B

HBeAg

270 HBeAg 25mg TDF 300mg

180 90 TDF 42.8

75.2% 93.7% 7.0% 28.5%

HBV DNA 5.8 log₁₀ IU/mL ALT 121U/L 53.3% 42.6%

HBV B C

48 48 HBV

DNA 20 IU/mL 48

HBeAg HBeAg

25mg QD TDF 3 96

4

	HBeAg		HBeAg	
	N=486	TDF N=246	N=180	TDF N=90
HBV DNA<20IU/mL	52.8%	55.9%	90.2%	92.9%
ALT	83.6%	78.4%	89.2%	90.8%
HBeAg /	17.6%/10.0%	17.2%/8.9%	NA	NA
HBsAg /	0/0	0/0	0.6%/0	0/0

ALT

ALT

NA=

4

	HBeAg		HBeAg	
	(N=486)	TDF (N=246)	(N=180)	TDF (N=90)
HBV DNA<20IU/mL	71%	71.2%	93.1%	94%
ALT	89.4%	85.1%	91.4%	91.7%
HBeAg /	28.6%/16.5%	26.8%/14.1%	NA	NA
HBsAg /	0.2%/0	0.4%/0	1.2%/0	0/0

ALT

ALT

NA=

(q1 q3)	0.00 (-2.10,2.00) (g/cm ²)	-2.05 (-3.90,0.15) (g/cm ²)	-0.50 (-2.40,1.40) (g/cm ²)	-1.90 (-3.90,-0.05) (g/cm ²)	1.00 (-4.00,6.00) μmol/L	2.00 (-4.00,6.44) μmol/L
,	-20.1,59.5 (g/cm ²)	-18.1,9.1 (g/cm ²)	-13.9,16.1 (g/cm ²)	-13.1,35.7 (g/cm ²)	-56.0,32.8 μmol/L	-20.0,28.0 μmol/L
()*	0.09(0.181) (g/cm ²)	-1.90(0.239) (g/cm ²)	-0.50(0.162) (g/cm ²)	-2.09(0.213) (g/cm ²)	0.01(0.375) μmol/L	1.13(0.492) μmol/L
*		1.99 (1.462,2.523)		1.59 (1.117,2.062)		-1.12 (-2.219,-0.027)
P		<0.001		<0.001		0.045

-)

HBV

DNA DNA HBV DNA
(DNA

HBV HepG2.2.15
EC₅₀ 1.42nM HepG2 CC₅₀>10000 nM

HepG2 ()
(rtV173L rtL180M rtM204V/I)
HBV (EC₅₀ < 2)
(rtL180M rtM204V + rtT184G rtS202G rtM250V) HBV
(rtA181T rtA181V rtN236T) HBV
rtA181V + rtN236T HBV
(EC₅₀ 3.7)

Ames

4

2 7 25 75 225mg/kg (25mg/ 10 29 86),225mg/kg

NOEAL 75mg/kg

NOAEL 225 mg/kg

NOAEL 75mg/kg

- (6~15)

25 75 225 mg/kg (AUC 25mg/

18 74 325) 225 mg/kg

NOAEL 75mg/kg

6~18

5 25 125mg/kg (AUC

25mg/

8 31 129) 125 mg/kg

5~6

1~12

NOAEL 125 mg/kg

- NOAEL 25mg/kg

6 (21)

10 30 100mg/kg (25mg/ 3.9 12 39)

100 mg/kg (F1)

NOAEL 100mg/kg

:

300mg

10 () 4 ()

(25mg/) 189 ()

63 ()

(25mg/) 189

	HBV			TFV
	TFV			
		5mg~80mg		
0.25~0.50				0.37 ~0.57
5mg~80mg		1		TFV
0.75~1.00		30.9~36.70		5mg~80mg
TFV 1				
	HBV		25mg	
t _{max}	0.25	h	C _{max}	156.6ng/mL
AUC ₀₋₂₄	AUC _{0-t}	AUC ₀₋		
	TFV		t _{max}	0.88h
C _{max}	11.7ng/mL		AUC ₀₋₂₄	AUC _{0-t}
			AUC ₀₋	
25 mg QD			AUC	

0~528h 85.0%
12.7% 72.3%

18

HBV TFV

18.07-541U/L

TFV

ALT

HBV TFV

