

" "% % !

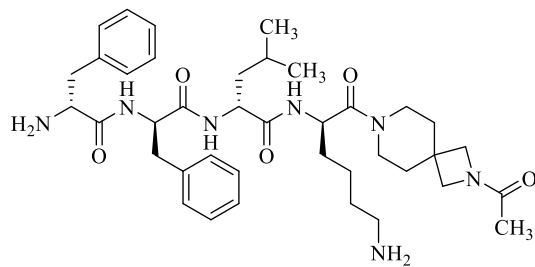
Anrikefon Injection

Anruikefen Zhusheye

-D-

-2-

-2 7- [3.5]



C₃₉H₅₇N₇O₅

703.93

1.

2.

1ml 0.1mg

5~20

2min

1h

10ml

24

0.9%

5%

1.0 µg/kg

 $1\sim 3$

8

1

0.3 µg/kg 1 3

/

18

			2	
III		HSK21542-301	HSK21542-303	
		HSK21542-301	136	
1.0µg/kg	135		≥1%	
	5.1%	2.2%	3.7%	
		1.5%	2.2%	
1			≥1%	
1		!		
		(N = 136)	(N = 135)	
5.1%				

	0	1.5%

HSK21542-303
 129

1.0µg/kg
 129
 129
 ≥1%
 7.8%
 8.5%
 8.5%
 3.9%
 2.3%
 2.3%
 2
 ≥1%

2

!

	- !")	- !")	- !")
	7.8%	41.1%	17.8%
	8.5%	37.2%	13.2%
	8.5%	0	0
	3.9%	0.8%	0.8%
	2.3%	0	0.8%
	2.3%	4.7%	4.7%
	0	2.3%	0

2
 ≥3

12 40 HSK21542

/ HSK21542

502 0.3 µg/kg 1 3

392 24 176

12

275 270

HSK21542 71 (25.8%) 47 (17.4%)

HSK21542 0.7%

0.4% 3 ≥1%

!

	~ - " %	- "
	12 (4.4)	5 (1.9)
	7 (2.5)	7 (2.6)
	14 (5.1)	7 (2.6)

	8 "!"%" - " %	- "
	3 (1.1)	3 (1.1)
	3 (1.1)	2 (0.7)

442 92 (20.8%)
0.9% 4

≥1%

!

	26 (5.9)
	16 (3.6)
	13 (2.9)
	5 (1.1)
	5 (1.1)
	5 (1.1)

%

38 ≥65 51 ≥65
HSK21542 11 (28.9%) 6 (11.8%)≥65
5 ≥65

% %

	8 "!" %"	- %
	- (	
	4 (10.5)	0
	0	1 (2.0)
	2 (5.3)	1 (2.0)
	0	1 (2.0)
	0	1 (2.0)
γ-	0	1 (2.0)
	1 (2.6)	0
	1 (2.6)	0
	1 (2.6)	0
	0	1 (2.0)
	1 (2.6)	1 (2.0)
	1 (2.6)	0
	2 (5.3)	0
	0	1 (2.0)
	1 (2.6)	0
	0	1 (2.0)

65 ≥65 16 24.6% ≥65

6 ≥65

%
7 / 17

	11 (16.9)
	2 (3.1)
	2 (3.1)
	1 (1.5)
	1 (1.5)
Y-	1 (1.5)
Q	1 (1.5)
QT	1 (1.5)
	1 (1.5)
	1 (1.5)
	1 (1.5)
	1 (1.5)

1 IV

2

3

18

	II	III		
≥65	21			
			65	
				III
	HSK21542		≥65	76

CYP1A2	CYP2B6	CYP3A4		CYP1A2	CYP2B6	CYP2C8
CYP2C9	CYP2C19	CYP2D6	CYP3A4/5			
				BCRP	P-	P-gp
		OATP 1B1	OATP1B3			OAT 1
OAT3		OCT 2				MATE
1	MATE2-K					

1

	2		
0.16 mL		1.888μg	
	13		
I			3.375μg/kg
	66.7%	4/6	33.3% 2/6
			16.7% 1/6

C-QT			QTc
		0.2~3.375 μg/kg	
		2 min	15 min
			1μg/kg
	, C _{max}	10.2 ng/mL	8.13 ng/mL
AUC _{0-t}	10.13 ng*h/mL	9.89 ng*h/mL	2 min
15 min			

3 0.3 μg/kg

		0.2~3.375 μg/kg	,
	227~274 mL/kg		
3	0.3 μg/kg		1.3 L/kg
	0.46~0.54	[¹⁴ C]	
			14.3%

[¹⁴C]

≤1.07%

0.2~3.375 µg/kg

t_{1/2} 1.39~2.24 h

46.30±12.02% 35.60±5.66%

3 0.3µg/kg

t_{1/2} 26.3 h

74.7±13.2% 0.621±0.871%

0.119±0.292%

N=159

(N=13)

N=281

AUC

7.88% 73.8% C_{max}

1 µg/kg

90≤GFR<130 mL/min, N=8

60≤GFR<90 mL/min,

N=8

30≤GFR<60 mL/min N=8

15≤GFR<30 mL/min N=9

AUC_{0-∞}

27.02% 62.79% 121.64% C_{max}

N=43

(N=11)

(N=15)

N=447

AUC 13.6% 51.2% 30.5%

AUC

AUC

AUC

33%

78%

PK

≥65

65

AUC

38.5%

≥65

65

AUC

4%

II

18-70

III

ASA

I-

271

136

135

8h

3

1.0μg/kg

2min

FAS

0-

24h

SPID

SPID_{0-24h}

-39.1

*h

-27.4

*h

95%

CI

-11.7 (-17.0

-6.5)

FAS

22.0 h vs 20.3 h

9.0

vs 8.4

8.9 vs 7.8

0-24h

33.1% vs 46.7%

2.3 mg vs 2.9 mg

PPS

FAS

94

61

SPID _{0-24h} *h	-!	-! %
	-39.1	-27.4
95%	-11.7 (-17.0, -6.5)	/
P	<0.0001	/

/

III

ASA

I-II 18-70

387

129

129

129

8h

3

1.0µg/kg

2min

FAS

SPID_{0-24h}

-64.0 * h -62.9 * h -45.9 * h

SPID_{0-24h}

95% CI -18.1(-24.4 -11.9) * h

SPID_{0-24h}

95% CI -17.0 (-23.2 -10.7)

* h

SPID_{0-24h}

95% CI -1.1(-

7.4 5.1) * h FAS

21.04 h 21.32 h 18.18 h

8.7 8.5 8.2

8.6 8.4

7.6 0-24h

40.3% 35.7%

71.3% 0-24h

29.8mg 29.3mg 61.6mg

(

94

61

SPID_{0-24h} *h -!")

-!")

-!")

95%	-18.1 (-24.4, -11.9)	-17.0 (-23.2, -10.7)	/
P	<0.0001	<0.0001	/
95%	-1.1 (-7.4, 5.1)	/	/
P *	0.0001	/	/

* -11.03 *h

HSK21542

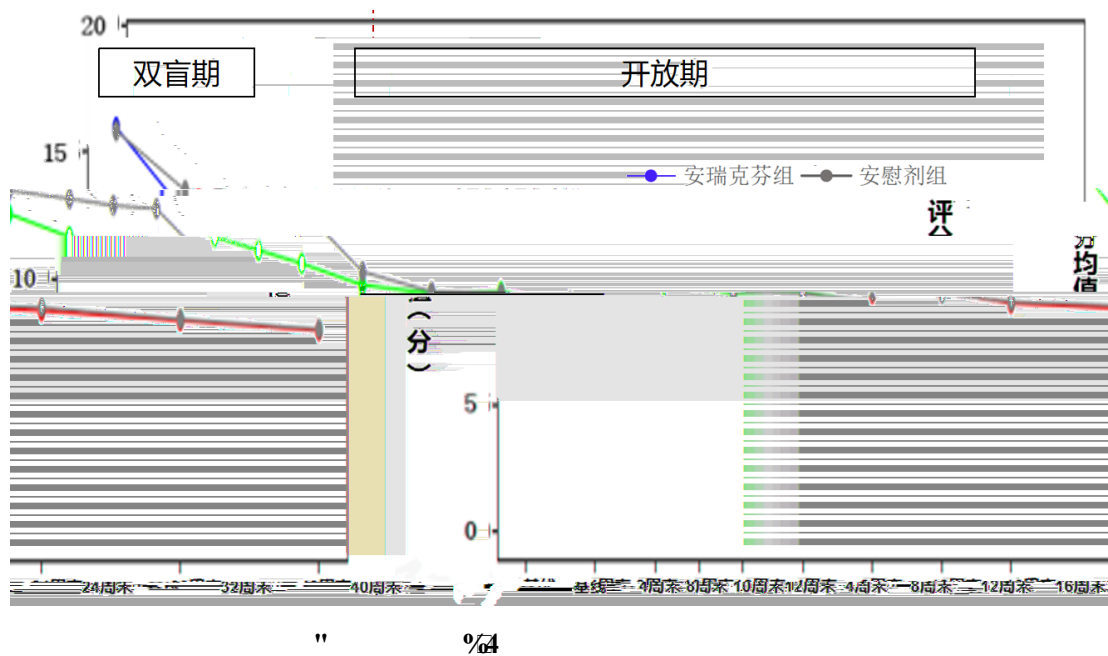
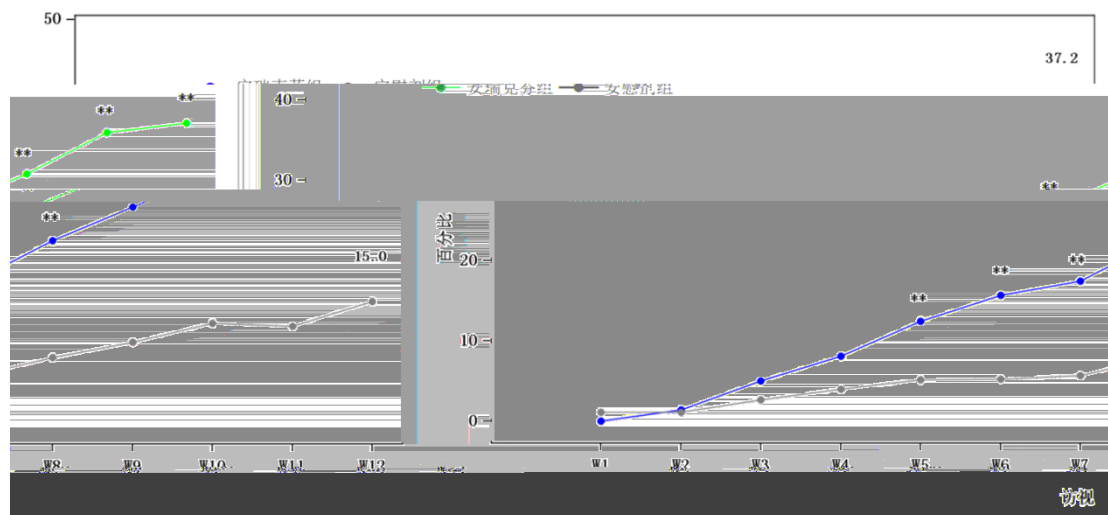
≥18 3

3 6

sp Kt/V ≥ 1.2 URR ≥ 65% sp Kt/V
 ≥ 1.2 URR ≥ 65% NRS 5

1:1 HSK21542 0.3µg/kg 1 3

12 12



K

KOR

Ames

2 7 1 3 10 mg/kg/ ≥1 mg/kg/

/

- 6~17

0.2 1 4 mg/kg/ [AUC MRHD 1µg/kg

19 82 358] 4 mg/kg/

- NOAEL 1mg/kg/ 7~19

0.3 1 2 µg/kg/ AUC MRHD 0.1 0.3 0.8

2 µg/kg/

6 21

0.2 1 4 mg/kg/ AUC MRHD 17 59 250

1 0.1 0.5 2.5 mg/kg/ AUC

MRHD 16 107 1609 10 60 425 RasH2

1 6 0.4 2 10 mg/kg/ AUC

MRHD 31 142 669 23 112 593

25

4 /

36

YBH08362025

H20250014

17

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