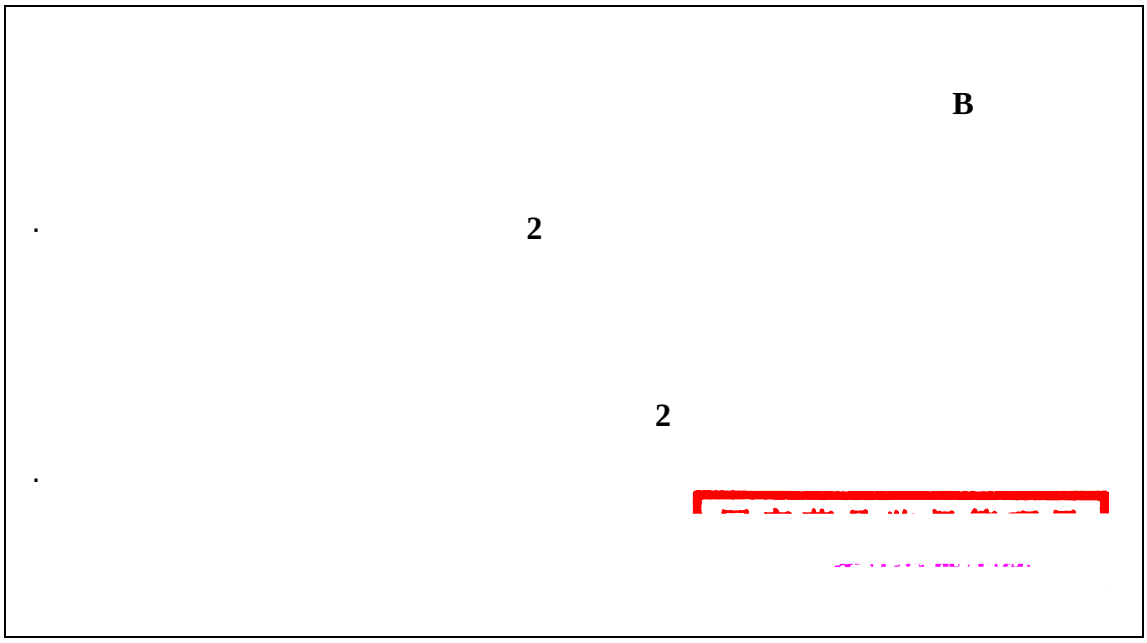


Ciprocopan Succinate Tablets

Huposuan Sipukepan Pian

4-((2 ,4)-4- -1-{[5-(- 3)-7- -1

PNH

100 mg $C_{26}H_{27}D_3N_2O_3$

200 mg

PNH

PNH

“ ”

“ ”

“ ”

MedDRA		

PNH 9 5.8%

1 2

24

2.00 U/L

.

.

. B

B

2

2

PNH

PNH PNH

156 1

LDH PNH

2 LDH

PNH

MAVE

AST

AST LDH

AST ALT γ -

GGT LDH

PNH

BTH 156 3 1.9% 2.0/100

4 BTH 3

1 2

156 5

≥20g/L LDH BTH

PNH

AUC

MRHD 200mg 8.5 5.8

PNH PNH

“ ”

18

156 5 3.2% ≥65 ≥65
<65 65

CYP2C8

CYP2C8 C_{max} AUC_{0-inf}
7% 85% CYP2C8

CYP2C8

CYP2C8 PBPK
CYP2C8 C_{max} AUC_{0-inf} 0.107%
65.5%
CYP2C8

375mg 600mg

PNH

200mg 4 AP

88.11% 24 AP 76.98%

PNH 200mg

1 Hb Hb

24 Hb 128 g/L 1

1 LDH

2 LDH >85% 18

24 4 3 LDH≤1.5 ULN

92%

C-QT 7230 ng/mL ΔΔQTcF 90% CI

10ms QTc

50~600 mg

T_{max} 3.50~4.00 h 200mg 7

C_{max} AUC 1.64 1.84

C_{max} AUC_{0-t} $AUC_{0-\infty}$

108.05% 98.73% 97.86% C_{max} AUC

200mg

102 L 0.646~0.851

CYP2C8

N- M13

12.7% 6.26% M3-2

M2-2 36.8% 15.8% 9.70%

200 mg /

65kg 5^{th}

	(N=37)	**(N=36)**
( )[1]	41.4(13.0) [18,70]	40.1(9.8) [22,61]
	14(37.8) 23(62.2)	22(61.1) 14(38.9)
( )[2]	7.1(5.1)	7.3(5.9)
(g/L)[2]	75.5(14.8)	73.0(14.6)
LDH U/L [2]	1982.2(864.9)	1774.8(750.3)
10^9/L [2]	238.4(83.7)	247.8(114.1)
PNH % [2]	55.0(23.6)	59.4(20.1)
n%	12(32.4)	16(44.4)
12 n%	18(48.6)	20(55.6)
6 n%	18(48.6)	17(47.2)
12 MAVE n%	1(2.7)	1(2.8)

[1] (SD) [,] [2] (SD)

2 18 24

4 3 ≥120g/L

18 24 ≥20 g/L

FACIT-

3 HSK39297-301

3 HSK39297-301 PNH 24

	(N=37) **95%CI**	**(N=36)** **95%CI**	**95%CI** **P**
2 18 24 4 3 ≥120g/L (%)[1,2,3]	22/37 59.5 (43.2, 75.7)	3/36 8.3 (2.8, 19.4)	51.1 (32.1, 70.0) <0.0001
[4]			

	(N=37) **95%CI**	**(N=36)** **95%CI**	**95%CI** **P**
2 18 24 4 3 ≥20g/L (%)[1,2,5]	34/37 91.9 (81.1, 100)	20/36 55.6 (38.9, 72.2)	9.2 (2.3, 35.9)

(g/L)

B FB

FB AP

Ames

50

150 450 mg/kg/ 28 14

14 GD7 450 mg/kg [

mg/m^2 MRHD 21.6]

- GD6-17

30 100 300 mg/kg/ 300 mg/kg AUC MRHD

8.5 /

/ - GD6~19

60 120 300 mg/kg/ AUC MRHD 5.8

-

GD6-PND21

50 100 300 mg/kg/ 300 mg/kg AUC

MRHD 6.2 F1

rasH2 26 60 120

300 mg/kg/ AUC MRHD 6

25

/ / 14 /

2 / 1 /

18

YBH20192026

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