



Edaravone and Dexborneol
Sublingual Tablets

C _{min} ng/mL		0.512 70.1	0.915 25.7	/
	RA _{C_{max}}	1.49 46.5	1.28 45.9	/
	RA _{AUC0-12h}	1.54 14.3	1.25 32.1	/
	C _{max} AUC			
		-		
T _{max} h		0.500 0.250~0.750	0.500 0.500~1.00	0.625 0.167~0.750
~		0.250 0.250~0.500	0.500 0.500~0.750	/
T _{1/2} h		2.40 71.1	1.64 32.7	3.16 28.3
		4.02 28.1	7.90 52.1	/
		30mg	6mg	

z	2.66
P	0.0079

mRS

90 mRS ≤2

76.0% 342/450 72.6% 337/464

NIHSS 14 -3.3±0.2 -3.2±0.2 30

-4.8±0.1 -4.5±0.1 90 -5.8±0.1 -5.6±0.1

NIHSS 0-1 14 15.0%

16.2% 30 35.9% 32.2% 90 57.2% 51.6%

63.8~75.5%

63.0~68.4%

V_z/F

23.9~25.8L

V_z/F 27~33.6L

V_z/F 738~1720L

V_z/F

1210~2727L

Ames

⊗

4

25mg/kg

6

25mg/kg

6.25 12.5

⊗

24h

82%

4.17%

63%

1

2

3

t_{1/2}

2.87~3.67h

t_{1/2}

1.64~3.16h

1

2

t_{1/2}

4.02~7.90h

t_{1/2}

3.76~4.36h

6

18

2.5 5 10mg/kg

6

6.25 12.5 25mg/kg

21

F0 F1

25,

/

/

6

/

1

/

14

/

1

/

1.73m²

30mg

eGFR 60~89mL/min/
60min

24

YBH27462024

H20240041

C_{max}

AUC_{0-∞}

1.15

1.20

eGFR

30~59mL/min/1.73m²

1.25

1.29

99

210032

Child-Pugh score 5 6

60min

Child-Pugh score

Child-Pugh score 10~14

99

210032

025-58286999

025-58285555

www.simcere.com

8008289800

4008877552

5

6

≥2

914

NIHSS

6-20

450

1

2

/

464

14

90 mRS

≤1

64.4% 290/450 54.7% 254/464

9.7%

(95%CI: 3.4, 16.0) OR 1.50 95%CI 1.15 1.96 P = 0.0029

90 mRS

Wilcoxon

P=0.0079

mRS

(FAS)

		(N=450)	(N=464)
90 n(%)	0	123(30.1)	113(26.3)
	1	160(39.2)	138(32.1)
	2	49(12.0)	82(19.1)
	3	50(12.3)	49(11.4)
	4	22(5.4)	37(8.6)
	5	4(1.0)	11(2.6)
		408(100.0)	430(100.0)



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