

Edaravone and Dexborneol Sublingual Tablets
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1
(1,2,4)-1,7,7- - [2.2.1] -2-

C₁₀H₁₈O
154.25

2
3- -1- -2- -5-

C₁₀H₁₀N₂O
174.20

30mg 6mg

1 2 6

14

III
+ ũ p
r = 5 5 d

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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%

23.9~25.8L Vz/F 738~1720L Vz/F 27~33.6L Vz/F 1210~2727L

Ames

25mg/kg 25mg/kg

24h

82% 63%

4.17%

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

eGFR 60~89mL/min/60min eGFR

1.73m² 30mg 1.15 1.20

30~59mL/min/1.73m² 1.25 1.29

6.25 12.5

25mg/kg 25mg/kg

6 15

6.25 12.5 25mg/kg 25mg/kg

6 18 2.5 5 10mg/kg

6 21 F0 F1

6.25 12.5 25mg/kg

25

/ / 6 / 1 / 14 / 1 /

24 YBH27462024 H20240041

Child-Pugh score 5 6

60min Child-Pugh score

Child-Pugh score 10~14

30mg 1.20 1.07

C_{max} AUC_{0-∞} 1.24 1.14

7~9 1.20 1.19

210032 99

210032 99

025-58286999

025-58285555

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914 NIHSS 6-20

5 6 ≥2 450 14

1 2 / 464

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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