

Edaravone and Dexborneol Sublingual Tablets
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1

(1, 2, 4)-1,7,7- - [2.2.1] -2-

$C_{10}H_{18}O$
154.25

2

3- -1- -2- -5-

$C_{10}H_{10}N_2O$
174.20

30mg 6mg

1

2

6

14

III

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 0.625
 T_{max} h 0.167p0.750
 P

mRS
90 mRS 2
.51 76.0% 342/450 72.6% 337/464
NIHSS 14 -3.3f 0.2 -3.2f 0.2 30
-4.8f 0.1 -4.5f 0.1 90 -5.8f 0.1 -5.6f 0.1
NIHSS 0-1 14 15.0%
16.2% 30 35.9% 32.2% 90 57.2% 51.6%

63.0p68.4% 63.8p75.5%
23.9p25.8L VI / F 27p33.6L VI / F
1210p2727L VI / F 738p1720L VI / F
Ames
2 6 4 6.25 12.5
25mg/kg 25mg/kg
4.17% 82% 63%
6 15
6.25 12.5 25mg/kg 25mg/kg
6 18 2.5 5 10mg/kg
6.25 12.5 25mg/kg 6 21 FO F1
25
/ / 6 / 1 / 14 / 1 /
1.73m² 30mg eGFR 60p89mL/min/60min eGFR 24
 C_{max} AUC₀₋ 1.15 1.20 YBH27462024
30p59mL/min/1.73m² 1.25 1.29 H20240041
Child-Pugh score 5 6
60min
Child-Pugh score
Child-Pugh score 10p14
210032 99
210032
025-58286999
025-58285555
www.simcere.com
8008289800
4008877552
5 6 2 914 NIHSS 6-20
1 2 / 464 450 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

	(N=450)	(N=464)
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)