

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

2
C₁₀H₁₈O
154.25
3- -1- -2- -5-

C₁₀H₁₀N₂O
174.20
! ! ! ! ! k
k
!
k
30mg 6mg k

14 k 1 k 2 6
k
k
k

III
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Edaravone and Dexborneol
Sublingual Tablets

C _{min} ng/mL	0.512 70.1	0.915 25.7	x	2.66
RA _{Cmax}	1.49 46.5	1.28 45.9	P	0.0079
RA _{AUC0-12h}	1.54 14.3	1.25 32.1	mRS	
T _{max} h	C _{max} AUC		k	
I	0.625		90 mRS ≤2	
	0.167 0.750		k	
	.51 76.0% 342/450		72.6% 337/464	
	NIHSS		14	
	-4.8@0.1		90	
	NIHSS		0-1	
	16.2%		35.9% 32.2%	
	30		90	
			57.2% 51.6%	
	63.8 75.5%		k	
63.0 68.4%	k		/	
23.9 25.8L	Vx/F 27 33.6L		k	
1210 2727L	Vx/F 738 1720L		Vx/F	
	Ames		k	
	«		4	
	k		6.25 12.5	
	2		6	
	25mg/kg		25mg/kg	
	« 24h		k	
	k 82%		6 15	
4.17%	63%		6.25 12.5 25mg/kg	
t _{1/2}	1 12 13		2.5 5 10mg/kg	
2.87 3.67h	t _{1/2}		6	
1.64 3.16h	t _{1/2}		21	
3.76 4.36h	t _{1/2}		F0 F1	
4.02 7.90h	k		k	
	k		25,	
	k		/ /	
1.73m ²	eGFR 60 89mL/min/60min		16 / 1 / 14 / 1 / k	
C _{max} AUC _{0-∞}	30mg		24 k	
30 59mL/min/1.73m ²	1.15 1.20		YBH27462024	
	1.25 1.29		H20240041	
	k		99	
	k		210032	
	Child-Pugh score 5 6		99	
C _{max} AUC _{0-∞}	30mg		210032	
7 9	1.20 1.07		025-58286999	
	1.24 1.14		025-58285555	
	1.20 1.19		www.simcere.com	
	k		8008289800	
	k		4008877552	
	k		!	
5	k		NIHSS	
6	≥2		6-20	
	1 2 / 464		450	
	k		14 k	
	90 mRS ≤1		k	
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	
k	90 mRS		Wilcoxon	
P=0.0079	k			

	(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)