Edaravone and Dexborneol Sublingual Tablets
Yidalafeng Youkanchun Shexiapian

k

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

! ! ! ! ! k

k

! k

30mg 6mg k

1 2 6
14 k k

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	
	RA_{cmax}	1.49 46.5	1.28 45.9	
	$RA_{AUC0-12h}$	1.54 14.3	1.25 32.1	

! C_{max} AUC k

-

T_{mjax} h		0.625
		0.167|0.750.M

|

63.8|75.5%
63.0|68.4% k
Vx/F
23.9|25.8L Vx/F 27|33.6L
Vx/F 738|1720L Vx/F
1210|2727L k

k

«

k

k

« 24h
k 82%
4.17% 63%
k

1 !2 !3
$t_{1/2}$ 2.87|3.67h $t_{1/2}$ 1.64|3.16h k 1
!2 $t_{1/2}$ 3.76|4.36h
$t_{1/2}$ 4.02|7.90h k

k

k

k

eGFR 60|89mL/min/
1.73m² 30mg 60min
C_{max} $AUC_{0-\infty}$ 1.15 1.20 eGFR
30|59mL/min/1.73m² 1.25 1.29 k !
k

k

k

Child-Pugh score 5 6
30mg 60min
C_{max} $AUC_{0-\infty}$ 1.20 1.07 Child-Pugh score
7|9 1.24 1.14 Child-Pugh score 10|14
1.20 1.19 k ! !
k

k

! !
k 914 NIHSS 6-20
5 6 ≥ 2 450
1 2 / 464 14 k
k
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
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)

x 2.66
P 0.0079

mRS k
90 mRS ≤ 2
.51. 76.0% 342/450 72.6% 337/464 k
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 k
NIHSS 0-1 14 15.0%
16.2% 30 35.9% 32.2% 90 57.2% 51.6% k

k

/
k

Ames !
k

4 !
2 6 6.25 !12.5 !
25mg/kg 25mg/kg
!
k
- 6 15
6.25 !12.5 !25mg/kg 25mg/kg
-
6 18 2.5 !5 !10mg/kg
- k
6 21
6.25 !12.5 !25mg/kg F0 F1 k
k

25, k

/ / !6 / 1 / 14 / 1 / k

24 k
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