Edaravone and Dexborneol Sublingual Tablets
Yidalafeng Youkanchun Shexiapian

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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

! ! ! ! ! k

k

! k

30mg 6mg k

1 2 6

14 k k

k

k

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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

0.625

$T_{mjx}$ h 0.167|0.750

63.8|75.5%

63.0|68.4%

Vx/F

23.9|25.8L Vx/F 27|33.6L

Vx/F 738|1720L Vx/F

1210|2727L

82%

4.17% 63%

1 2 3

$t_{1/2}$ 2.87|3.67h $t_{1/2}$ 1.64|3.16h 1

2 $t_{1/2}$ 3.76|4.36h

$t_{1/2}$ 4.02|7.90h

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

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

914 NIHSS 6-20

5 6 ≥2 450

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

.

| | (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

90 mRS ≤2

.51. 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%

/

Ames

4 !

2 6 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

6.25 !12.5 !25mg/kg F0 F1

25,

/ / 6 / 1 / 14 / 1 /

24

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