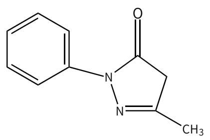
Edaravone and Dexborneol Concentrated Solution for Injection

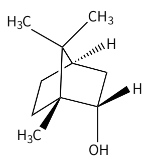
Edaravone and Dexborneol Concentrated Solution for Injection
Yidalafeng Youkanchun Zhusheyong Nongrongye

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

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



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



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

/

pH

5ml 10mg 2.5mg

15ml 30mg 7.5mg
2 100ml 30
14 48

III

III 1194
599 1
37.5mg/ 26.98 1 28

13.7% 82 >1% 28 4.7%
12 2.0%
0.1%～1.0% :
1. 2.7%

2. 1.2%

3. 1.0%

4. 0.8%

5. 0.7%

6. 0.5%

7. 0.5%
8. 0.3%
9. 0.3%
10. 0.3%
11. 0.3%
12. 0.2%
13. 0.2%
14. 0.2%
8.0%
γ

α

1.
2.

1.
2.
3.
4.

80

1.

6.25-25mg/kg/day
2.9 -
2

80

UGT
CYP450 ,
UGT
CYP

1. F1

2.
3.

4. 15mg/3.75mg-60mg/15mg
5.
30mg/7.5mg
23.4L 500 5000 50000ng/mL
120mg/ 30mg 2 60mg/ 76% 73% 64%
15mg 5

37.5mg 24h
SIM-23-02 45 , 82%
III n=1194 n=599 4.17% 63%
n=595 $t_{1/2}$
48 37.5mg 3.2h $t_{1/2}$ 2.1h
30mg 14 $t_{1/2}$ 2.0h

90 mRS ≤1 65.44%
57.65% 7.79% 95%CI 2.29%,13.30%
P=0.0056 14 30 90 5ml/ 6 /
NIHSS -3.01 -3.22 -4.08
-2.60 -2.85 -3.80 24
14 30 90 NIHSS
-0.42 95%CI -0.73~-0.10 P=0.0097 -0.39 YBH02562020
95%CI -0.72~-0.07 P=0.0147 -0.33 95%CI -0.64~-0.01
P=0.0359 SIM-23-02 H20200007

99
210032

/ 99
210032
025-58286999
025-58285555
Ames www.simcere.com

8008289800
4 4008877552
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

P21640503