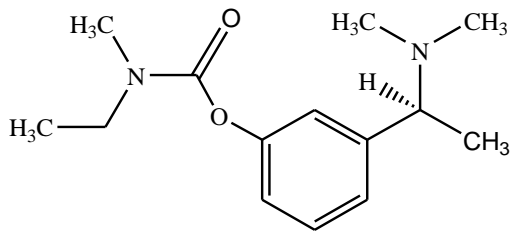




Rivastigmine Transdermal Patch
Lisidiming Toupitieji

S -N- -N- -3-[1-()]-



C₁₄H₂₂N₂O₂

250.34

[(2-) ,]
/ /

4.6mg/24

1 4.6mg/24

2 9.5mg/24

- 50kg

-

| | | | | | | |
|-----------|----------|-----|-----------|-----------|-------------|---|
| | | | 4.6mg/24 | 9.5mg/24 | 13.3mg/24 | |
| 17.4mg/24 | | | | 13.3mg/24 | 17.4mg/24 | |
| | | | | | | 1 |
| | 9.5mg/24 | | | | | |
| / | | | | | / | |
| | | | 17.4mg/24 | * | | |
| | | | | 9.5mg/24 | | |
| 2 | | | | | | |
| | | 1 2 | | | | |
| (10%) | (1%~10% | 1%) | (0.1%~1% | 0.1%) | (0.01%~0.1% | |
| 0.01%) | (<0.01%) | | | | | |
| 1 | | | | | | |

| |
|--|
| |
| |
| |
| |

* 13.3mg/24

* 17.4mg/24

** 24 " "

*** 24 " "

/

| | | | | | |
|--|--------|---------|---------|--------|---------|
| | 18 6.2 | 57 18.8 | 50 17.0 | 10 3.3 | 75 12.6 |
| | 18 6.2 | 31 10.2 | 16 5.4 | 10 3.3 | 49 8.2 |
| | 8 2.7 | 23 7.6 | 16 5.4 | 4 1.3 | 31 5.2 |
| | 7 2.4 | 21 6.9 | 22 7.5 | 7 2.3 | 28 4.7 |
| | 2 0.7 | 15 5.0 | 12 4.1 | 3 1.0 | 17 2.9 |
| | 10 3.4 | 13 4.3 | 18 6.1 | | |

2.2%

3.7%

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- /
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3

4.6mg/24

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QT /

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88% 65

55% 75

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P450

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/

/

/

/

-

/

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n=75

549

12mg/

/

/

23%

/

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/

/

24

48

24

10-20

24

ADAS-Cog
ADCS-CGIC

ADCS-ADL

3

24

4

4

3

24

| ITT-LOCF | 9.5mg/24 N=251 | 12mg/ N=256 | N=282 |
|-----------------------|---|---|--------------------------------|
| ADAS-Cog ± 24 ± | n=248 27.0±10.3 -0.6±6.4 0.005* ¹ | n=253 27.9±9.4 -0.6±6.2 0.003* ¹ | n=281 28.6±9.9 1.0±6.8 |
| ADCS-CGIC ± p | n=248 3.9±1.20 0.010* ² | n=253 3.9±1.25 0.009* ² | n=278 4.2±1.26 |
| ADCS-ADL ± 24 ± | n=247 50.1±16.3 -0.1±9.1 0.013* ¹ | n=254 49.3±15.8 -0.5±9.5 0.039* ¹ | n=281 49.2±16.0 -2.3±9.4 |

* p 0.05
ITT
1 LOCF

ADAS-Cog

ADCS-ADL

2 CMH van Elteren ADCS-CGIC <4

24

5

ADAS-Cog

4

ADCS-CGIC

ADCS-ADL

| | | | |
|------------------------------------|----------|--------------------|-------|
| | % | | |
| | 9.5mg/24 | 12mg/ [®] | |
| ITT-LOCF | N=242 | N=248 | N=276 |
| ADAS-Cog 4 ADCS-CGI ADCS-ADL | 17.4 | 19.0 | 10.5 |
| p | 0.037* | 0.004* | |

* p<0.05

9.5mg/24

12mg/

9.5mg/24

48

MMSE

10-24

24-48

9.5mg/24

13.3mg/24

9.5mg/24

48

MMSE

2

3

ADAS-Cog

-

ADCS-IADL

-

2

48

6

6

ADAS-Cog

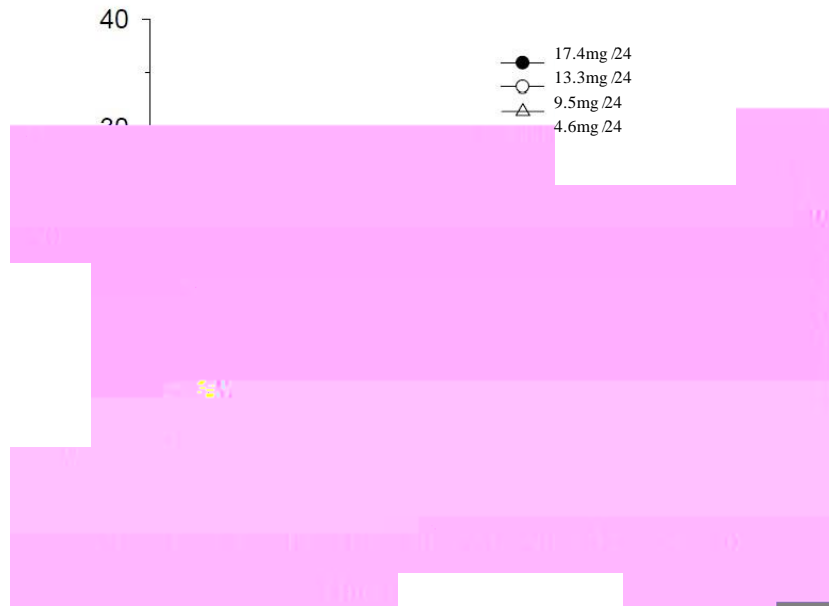
ADCS-IADL

| | | | |
|--|-------------------------|------------------------|----------------------------------|
| | (13.3mg/24h) N = 265 | (9.5mg/24h) N = 271 | - (13.3mg/24h) (9.5mg/24h) |
| | | | DLSM 95% CI P |

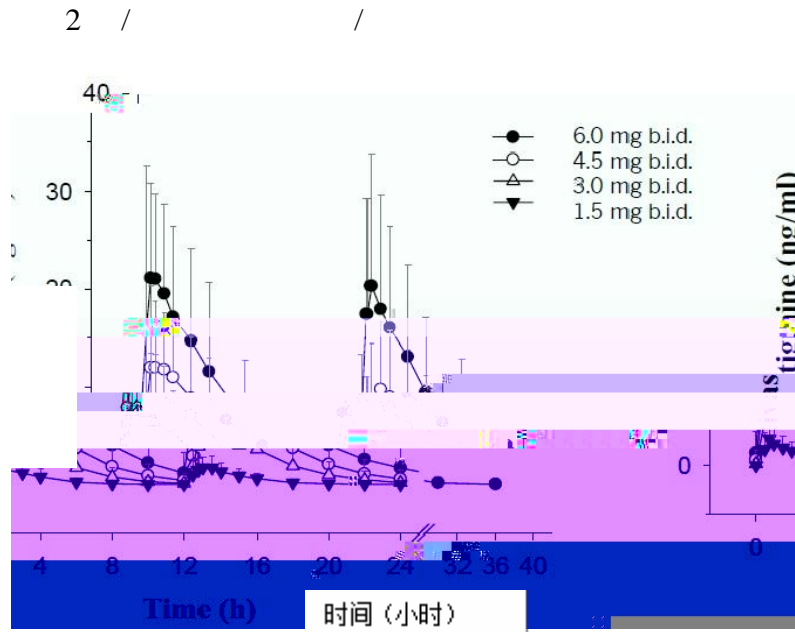
| | | | | |
|--|-------------------------|------------------------|---|-----------------------------|
| | (13.3mg/24h) N = 265 | (9.5mg/24h) N = 271 | - | (13.3mg/24h) (9.5mg/24h) |
|--|-------------------------|------------------------|---|-----------------------------|

-48

1 24



2



74% 103% 43% C_{max} 49% AUC_{0-24h}

71% 73% 45% C_{max} 43% AUC_{0-24h}

NAP-226-90

65kg
100kg

35kg

2

15

15

264670

0535-6717618

0535-6717718

www.luye.cn

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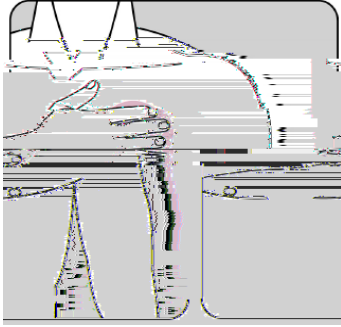
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