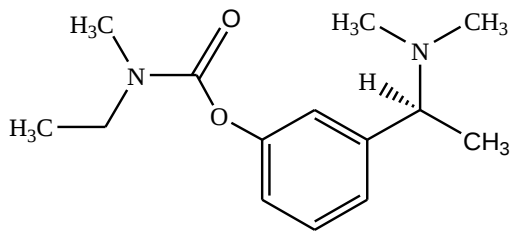




Rivastigmine Transdermal Patch

Lisidiming Toupitieji

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



C<sub>14</sub>H<sub>22</sub>N<sub>2</sub>O<sub>2</sub>

250.34

[(2- ) , ]  
/ /

4.6mg/24

1 4.6mg/24

2 9.5mg/24



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- 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      | Æ      | ó        |     |          |       |             |



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

| %      |                    |       |
|--------|--------------------|-------|
| 24     | 12mg/ <sup>®</sup> |       |
| N=242  | N=248              | N=276 |
| 17.4   | 19.0               | 10.5  |
| 0.037* | 0.004*             |       |

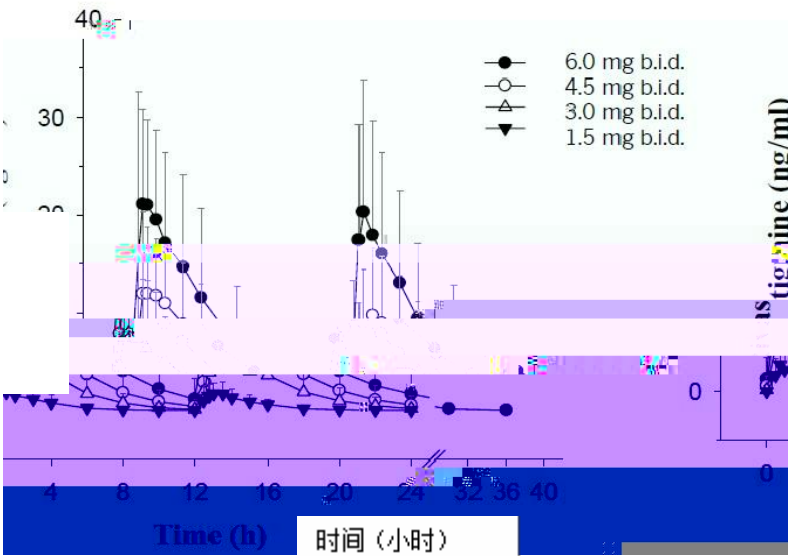
|          |          |           |       |
|----------|----------|-----------|-------|
| 4        | 12mg/    |           |       |
| 4        |          |           |       |
|          | MMSE     | 10-24     | 24-48 |
| 9.5mg/24 |          | 13.3mg/24 |       |
| 48       |          |           |       |
|          |          |           | MMSE  |
|          | ≥3       | ADAS-Cog  |       |
|          |          | ADCS-IADL |       |
| 2        | 48       | 6         |       |
|          | ADAS-Cog | ADCS-IADL |       |

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

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

-48





/ kg

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

74% 103%

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

71% 73%

|       |      |            |
|-------|------|------------|
|       |      | NAP-226-90 |
| 65kg  | 35kg | 2          |
| 100kg |      |            |

36

Luye Pharma AG  
Am Windfeld 35, 83714 Miesbach, Germany

**18 23**

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264670

0535-6717618

0535-6717718

[www.luye.cn](http://www.luye.cn)

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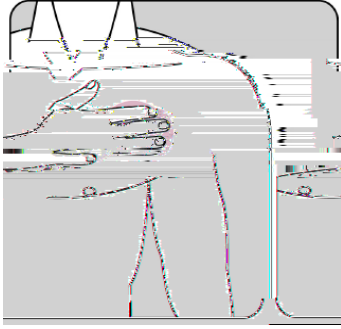
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