2020 06 02

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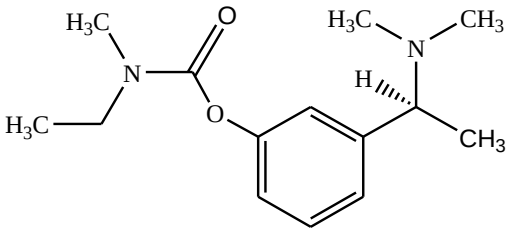
Rivastigmine Transdermal Patch

Lisidiming Toupitieji

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



$C_{14}H_{22}N_2O_2$

250.34

[(2-) ,]

/ /

4.6mg/24

1 4.6mg/24 2 9.5mg/24

- 50kg

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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 Ɓ Ű

* 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
[redacted]	10 3.4	13 4.3	18 6.1		

2.2% 3.7%

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3 4.6mg/24

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QT /

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88% 65 55% 75

/ P450

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β-

β- /

β-

β-

n=75 549

12mg/ /

/ 23%

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/

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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	n=248	n=253	n=281
±	27.0±10.3	27.9±9.4	28.6±9.9
24 ±	-0.6±6.4	-0.6±6.2	1.0±6.8
p	0.005*[1]	0.003*[1]	
ADCS-CGIC	n=248	n=253	n=278
±	3.9±1.20	3.9±1.25	4.2±1.26
p	0.010*[2]	0.009*[2]	
ADCS-ADL	n=247	n=254	n=281
±	50.1±16.3	49.3±15.8	49.2±16.0
24 ±	-0.1±9.1	-0.5±9.5	-2.3±9.4
p	0.013*[1]	0.039*[1]	

* p≤0.05

ITT LOCF

1 ADAS-Cog ADCS-ADL

2 CMH van Elteren ADCS-CGIC <4

24 5

ADAS-Cog 4 ADCS-CGIC ADCS-ADL

		%
24	® 12mg/	
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

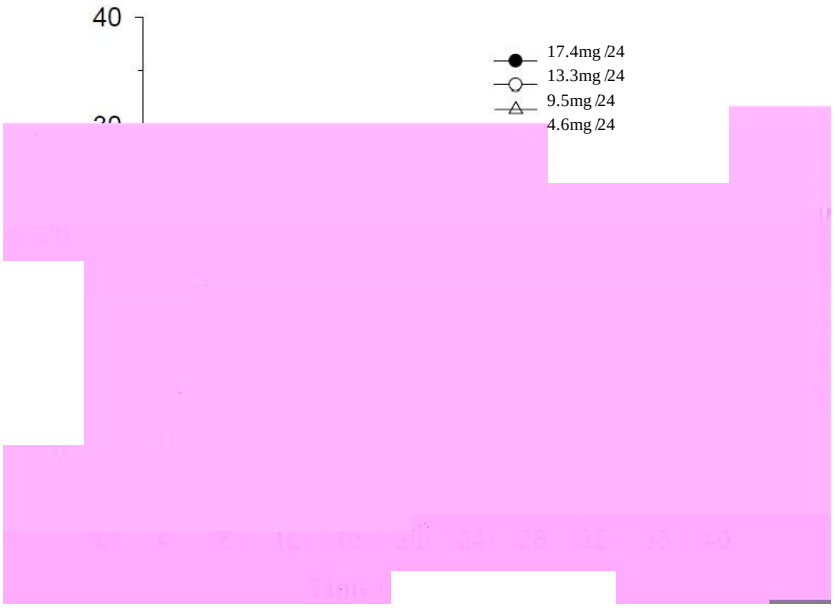
3.3mg/24h) N = 265	(9.5mg/24h) N = 271	(13.3mg/24h) - (9.5mg/24h)

DLSM P

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

-48

1 24



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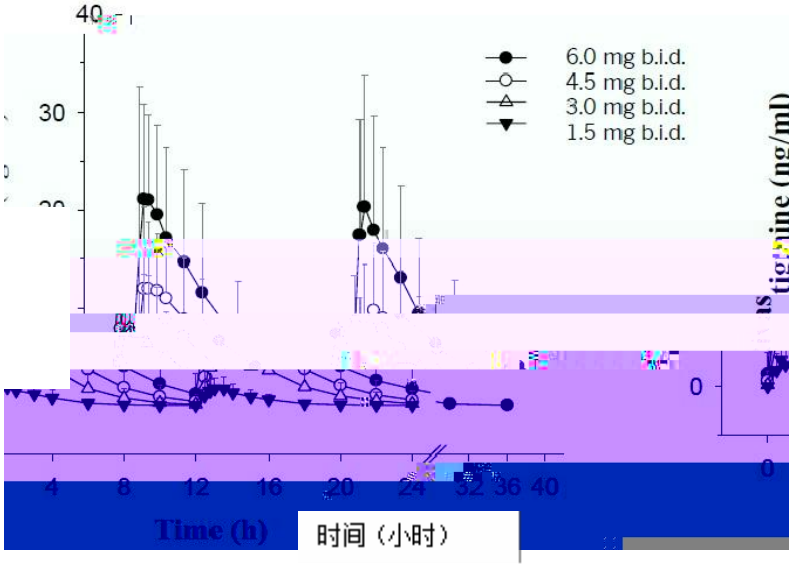

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/ kg 43% C_{max} 49% AUC_{0-24h}
74% 103%

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

NAP-226-90

65kg 35kg 2

100kg

/

C_{max} 60% AUC 2

3mg 6mg /

n=7, Child-Pugh 5-6 n=3, Child-Pugh 7-9 n=10,

n=10 60-65%

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7 / 30 /

36

JX20200001

Luye Pharma AG

Am Windfeld 35, 83714 Miesbach, Germany

Luye Pharma AG

Am Windfeld 35, 83714 Miesbach, Germany

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www.luye.cn

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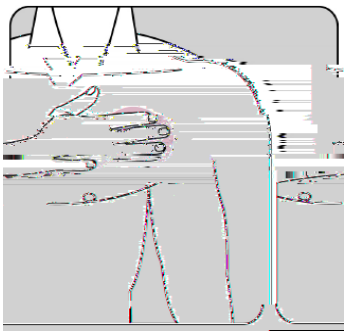

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