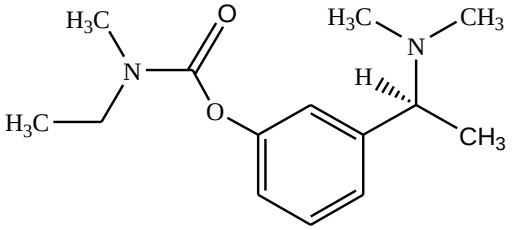
2020 06 02

外

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

-

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 Ƀ 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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Î ۜگ ۑ /

88% 65 55% 75

/ P450

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/ /

/

/

β-

β- /

β-

β-

n=75 549

12mg/ /

/ 23%

/

/

/

/ /

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 ± p	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 ± p	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 LOCF

1 ADAS-Cog ADCS-ADL

2 CMH van Elteren ADCS-CGIC <4

24 5

ADAS-Cog 4 ADCS-CGIC ADCS-ADL

5 24

	%		
	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

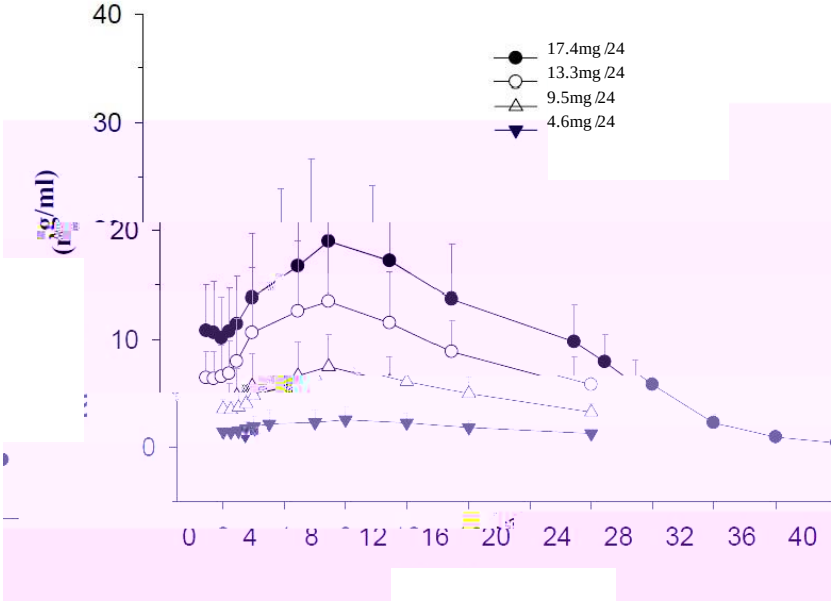
6 ADAS-Cog ADCS-IADL

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

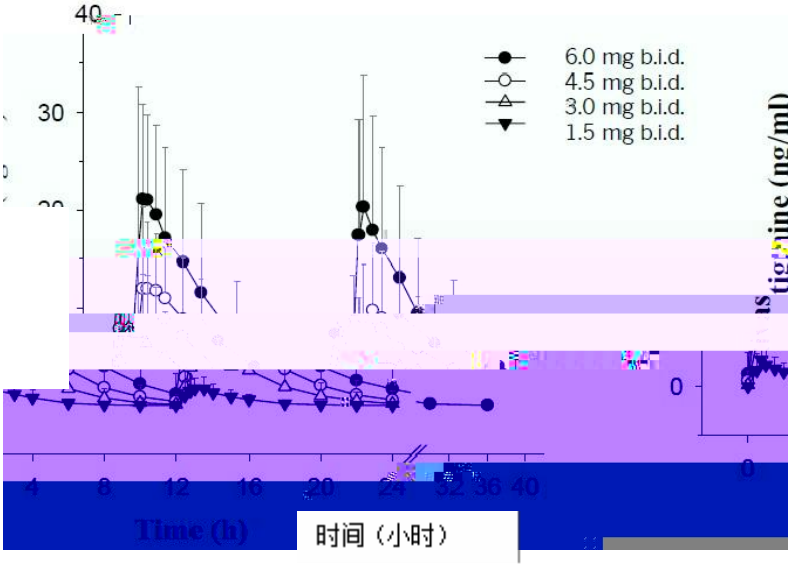
	(13.3mg/24h) N = 265	(9.5mg/24h) N = 271	(13.3mg/24h) - (9.5mg/24h)

-48

1 24



2 2 / /



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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%

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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264670

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0535-6717718

www.luye.cn

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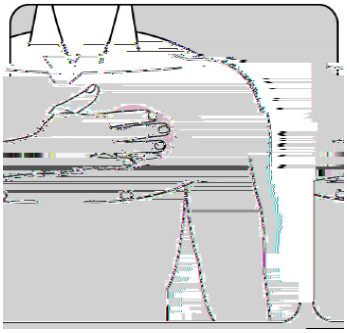

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