2021 10 26

2021 12 30

合源® 思源清®

/ **ADHD**

ADHD

/

6 **18**

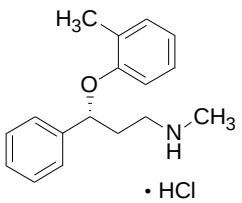
12 **2200** **11** **ADHD** **1**

0.4% **5/1357** **851**

Atomoxetine Hydrochloride Capsules

Yansuan Tuomoxiting Jiaonang

- -N- -3- -3- O-



$C_{17}H_{21}NO \cdot HCl$

291.82

/ ADHD

25mg($C_{17}H_{21}NO$)

70 - 0.5mg/kg

3 1.2mg/kg

1.2mg/kg/

1.4mg/kg 100mg

70 - 40mg

3 80mg

2 4 100mg

70kg 100mg

/

ADHD 6-15

1.2-1.8mg/kg/

120mg 150mg

- HI ADHD HI

Child-Pugh ClassB HI 50% HI

Child-Pugh ClassC 25%

CYP2D6 CYP2D6 Poor metabolizers,PM

_____- CYP2D6 CYP2D6 PM

70 0.5mg/kg/ 4

1.2mg/kg/

CYP2D6 70

40mg/ 4

80mg/

/

ADHD DSM-IV 7 -

2

	2	1
	3	0
	16	4
	3	1
	19	15
c	11	4
	5	2
	2	1

a 2%

2%

b

c

2 **18**

	BID		**QD**	
	N=715	**N=434**	**N=882**	**N=500**
a	17	13	18	7
	11	8	11	4
	7	6	13	4
b	2	1		

[c]	2	0	1	1

[a]

[b] Breslow-Day

[c] Breslow-Day 0.05 P 0.1

EM È 2% CYP2D6 PM PM

CYP2D6 EM PM 11%,EM 6% PM 7% EM 4% ×ï„.±Võo1U V÷ D

PM 7% EM 4% [1]

Ó65

	3	1
	20	5
	26	6
	8	3
b	7	4
	4	

f	8	1
g	3	2
f / f	4	1
	4	1
	3	0

a 2%

2% ґ

d

b ґ

c

D17À1Àna 6p N6691@

4 2%

_____-QT

_____-

_____-

_____-

_____-

_____-

_____-

ADHD

_____-

_____-

MAOI

MAOI MAOI MAOI

MAOI

15-20mmHg 20 /

/ ADHD

6 18

6000

1

120 [20 × ULN]

2 × ULN 40

12

:

-

- ADHD

:

a

	b				b			
	%	%	%	%	%	%	%	%
DBP	21.5	14.1	9.3	4.8	12.6	8.7	4.8	3.5
SBP	12.5	8.7	4.9	3.3	12.4	7.8	4.2	3.2
HR	23.4	11.5	12.2	3.8	22.4	8.3	10.2	2.0

a :bpm= / :DBP= HR= mmHg= SBP=

b

0% 0/934

0Ä3%

0.3%

0.2% 1939

4 1056

ADHD

:

ADHD ADHD

21/1308 1.6%

9/806 1.1%

1.33[95% 0.67-2.64-] 6/1697 0.35%

4/1560 0.26%

1.38[95% 0.39-4.88-]

ADHD

9-12

3 17.9

0.5 12

3 19.4 0.4 1

1:

CYP2D6

AUC 10 5 7% PM,)· EE9Ö2,ß)· EEÂYS(AQCYHÊ2D6

0.8mg/kg/ , 1.2mg/kg/ 1.30mg/kg/

± 0.29mg/kg/ PARS

158 26 16%

16 18-65 442

ADHD DSM-IV 23% 2

40mg/ 100mg/ 83mg/ ± 19.5mg/

LSAS

413 149 36.1%

_____-

_____-

_____-

_____-

4

_____-

_____-

____-

____- 24 24

_____-

____

CYP2D6

EM CYP2D6

PM

EM AUC 6 8 C_{ss} C_{max} 3 4

PM P450

2

600mcg 2 60mg 5

21

206A0 10.56 Tf7618C44 42[illegible]

,

pH

pH /

1400mg

QT

- 6 18 4

ADHD DSM-IV

/

ADHD ADHD Rating Scale-IV-Parent Version ADHDRS

/

intent-to-treat ADHDRS

DSM-IV

2 6 16 N=171 6

1.5mg/kg/ 1.3mg/kg/ ADHDRS

ADHD

2 7 13 3 N=147 4 N=144 9

CAARS ADHD

<42

/ ADHD

2 47 458mg/kg/

8 5 mg/m^2

AUC AUC 1.8 0.2

39 26 mg/m^2

10

1 10 50mg/kg/ mg/m^2 0.2 2

8

0.85L/kg

98%

_____- CYP2D6 EM

PM EM PM

AUC 10 Css Cmax 5 CYP2D6 PM

CYP2D6

CYP2D6

CYP2D6 4-

4-

EM 1% PM 0.1% 4- CYP2D6

PM 4- P450 N-

CYP2C19 P450

EM 5% PM 45%

EM 0.35L/hr/kg 5.2

PM 0.03L/hr/kg 21.6 EM

PM AUC 10 Css Cmax 5 EM 4-

N- 6 8 PM N-

34 40

4- -*O*- 80%

17%

3%

/ 7 / 1 / 14 / 1 / 14 / 2 /

24

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