

2021 10 26

2021 12 30

合源® 思源清®

/ ADHD

ADHD

/

6

18

12

2200

11 ADHD

1

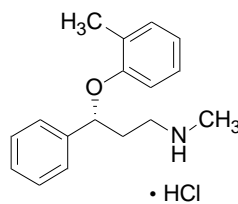
0.4% 5/1357

851

Atomoxetine Hydrochloride Capsules

Yansuan Tuomoxiting Jiaonang

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



C<sub>17</sub>H<sub>21</sub>NO·HCl

291.82

/ ADHD

25mg( C<sub>17</sub>H<sub>21</sub>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

1

0

c	2	0	1	1

a

b Breslow-Day

c Breslow-Day 0.05 P 0.1

**EM**

2%  
CYP2D6 EM

**F**

CYP2D6 PM  
PM 11%, EM 6%

PM  
PM 7% EM 4% x̄, ± V̄o1U V÷ D

PM 7% EM 4% 1

	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%

d

b

c

D1ĀĻĀnā 6p N67910

\_\_\_\_\_ -QT  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

ADHD

\_\_\_\_\_  
\_\_\_\_\_

MAOI

MAOI

MAOI

MAOI  
MAOI

15-20mmHg                      20 /

/                      ADHD

6    18

6000

1

“ ”

120

[ 20×

ULN ]

2× ULN

40

12

:

“ ”

---

-

-

ADHD

---

:

		15mmHg		20mmHg		20bpm <sup>a</sup>			
		b				b			
		%	%	%	%	%	%	%	%
DBP	15mmHg	21.5	14.1	9.3	4.8	12.6	8.7	4.8	3.5
SBP	20mmHg	12.5	8.7	4.9	3.3	12.4	7.8	4.2	3.2
HR	20bpm	23.4	11.5	12.2	3.8	22.4	8.3	10.2	2.0

<sup>a</sup> :bpm= / :DBP= HR= mmHg= SBP=

<sup>b</sup>

0% 0/934

0.3%

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-

]

9-12  
3 17.9  
0.5 12  
3 19.4 0.4 1

1:

AUC 10

5

7%

PM

CYP2D6

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

\_\_\_\_\_ -

\_\_\_\_\_ -



**CYP2D6**

EM	CYP2D6						
	PM						
EM	AUC	6	8	C <sub>ss</sub>	C <sub>max</sub>	3	4
	PM				P450		

2

600mcg

2

60mg

5

21

206A0 10.56 Tf7618C44 425-0a0B4

pH

pH /

1400mg

QT

\_\_\_\_\_ -

6 18

4

ADHD

DSM-IV

/

ADHD

ADHD Rating Scale-IV-Parent Version

ADHDRS

/

intent-to-treat

ADHDRS

DSM-IV

ADHD

1 8 18

N=297 8

0.5 1.2 1.8mg/kg/

ADHDRS

ADHD

1.8mg/kg/

1.2mg/kg/

0.5mg/kg/

2      6    16                      N=171      6

1.5mg/kg/  
ADHD

1.3mg/kg/

ADHDRS

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

CAARS

ADHD

<42 42

/ ADHD

2 47 458mg/kg/  
8 5 mg/m<sup>2</sup>  
AUC AUC 1.8 0.2  
39 26 mg/m<sup>2</sup>

10  
1 10 50mg/kg/ mg/m<sup>2</sup> 0.2 2  
8

0.85L/kg

98%

\_\_\_\_\_ - CYP2D6 EM

PM EM PM

AUC 10 C<sub>ss</sub> C<sub>max</sub> 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 C<sub>ss</sub> C<sub>max</sub> 5 EM 4-

N- 6 8 PM N-

34 40

4- -O- 80%

17%

3%

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

24

YBH12472021

H20213814

358

230088

0551-65368251 0551-65396630

0551-65396630

[www.heyuanpharm.com](http://www.heyuanpharm.com)

358

230088

0551-65368251 0551-65396630

0551-65396630

[www.heyuanpharm.com](http://www.heyuanpharm.com)