

2021 10 26

2021 12 30

合源® 思源清®

/ ADHD

ADHD

/

6

18

12

2200

11 ADHD

1

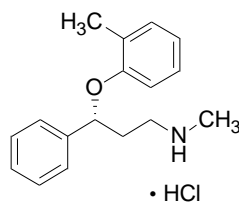
0.4% 5/1357

851

Atomoxetine Hydrochloride Capsules

Yansuan Tuomoxiting Jiaonang

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



$\text{C}_{17}\text{H}_{21}\text{NO}\cdot\text{HCl}$

291.82

/ ADHD

25mg(C₁₇H₂₁NO)

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% x i, . ± V õ o 1 U V ÷ D

PM 7% EM 4% 1

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 ^a			
		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

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

^b

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:

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_{ss} C_{max} 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/m²
 AUC AUC 1.8 0.2
 39 26 mg/m²

10
 1 10 50mg/kg/ mg/m² 0.2 2
 8

0.85L/kg

98%

_____ - CYP2D6 EM

PM EM PM

AUC 10 C_{ss} C_{max} 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_{ss} C_{max} 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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