

2021 10 26

2021 12 30

合源® 思源清®

/ ADHD

ADHD

/

6

18

12

2200

11

ADHD

1

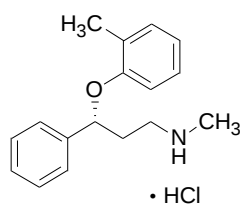
0.4% 5/1357

851

Atomoxetine Hydrochloride Capsules

Yansuan Tuomoxiting Jiaonang

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



C₁₇H₂₁NO·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

7

	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

2%

CYP2D6 PM

PM

CYP2D6 EM

PM 11%,EM 6%

PM 7% EM 4%

× i, .± Vño1U V÷ D

PM 7% EM 4% 1

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

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

:

	≥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
				Å

1:

		0.8mg/kg/	,	1.2mg/kg/	1.30mg/kg/
$\pm 0.29\text{mg/kg/}$					PARS
		158	26	16%	
16				18-65	442
ADHD	DSM-IV		23%		2
	40mg/		100mg/	83mg/	$\pm 19.5\text{mg/}$
			LSAS		
	413	149	36.1%		

_____ -

_____ -

“ ”

_____ -

_____ -

4

_____ -

_____ -

CYP2D6

EM	CYP2D6								
PM									
EM	AUC	6	8	C _{ss}	C _{max}	3	4		
	PM				P450				

β_2

600mcg	2					60mg	5
							21

206A0 10.56 Tf7618C44 425<Qa0B4

,

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 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 C_{ss} C_{max} 5 CYP2D6 PM

CYP2D6

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

YBH12472021

H20213814

358

230088

0551-65368251 0551-65396630

0551-65396630

www.heyuanpharm.com

358

230088

0551-65368251 0551-65396630

0551-65396630

www.heyuanpharm.com