

2021 10 26

2021 12 30

合源® 思源清®

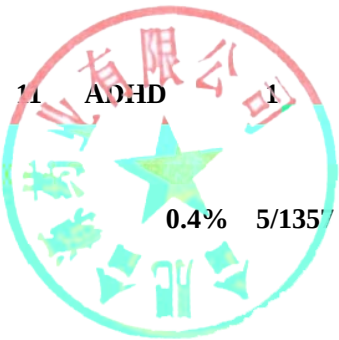
/ ADHD

ADHD

/

12

2200



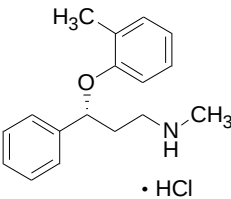
6 18

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

_____ -	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
	6	4	9	2

	3	1
	20	5
	26	6
	8	3
b	7	4
	4	2
	4	2
	10	6
	3	0
	2	1
	5	3
	2	1

4

2%

_____ -QT

_____ -

_____ -

_____ -

_____ -

_____ -

_____ -

_____ -

_____ -



ADHD

MAOI

MAOI

MAOI

MAOI

MAOI

15-20mmHg 20 /

/ ADHD

6 18

12 ADHD 11 1 2200

1357

851

0.4% 5/1357

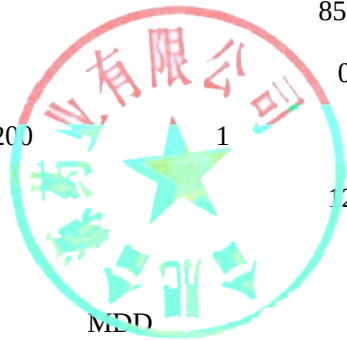
2200

1

12

ADHD

MDD



6000

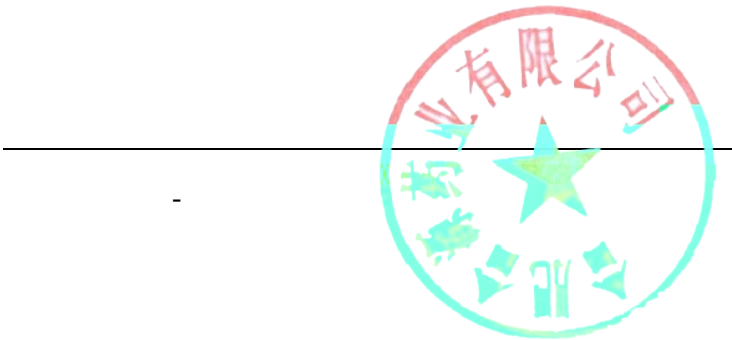
1

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

0.3% 5/1597

EM 5.0 / PM

9.4 /

EM/PM

PM

EM 11

/ 7.5 / PM

0.5% 2/402

1.5% 8/540

EM/PM

PM

EM 4.21 2.13mmHg ,

EM PM:2.75

EM:2.40mmHg PM

0.2% 12/5596

0.8% 46/5596

1.8% 6/340

0.5% 1/207

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% 0.39-4.08-

]

ADHD

1.7% 9/540

5.6%

30/540

0% 0/402

0.5% 2/402

2

4

		9-12		
			3	17.9
	0.5		12	
3		19.4		0.4
				1

1:

AUC	10	5	7%	PM	CYP2D6
PM	PM	CYP2D6		PM	

		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

_____ -

_____ -

_____ -

_____ -

24

24

_____ -

2-4% 15-20%



6

MAOI

CYP2D6

EM CYP2D6

PM

EM	AUC	6	8	C_{ss}	C_{max}	3	4
	PM				P450		

2

600mcg 2

60mg	5
------	---

21

80mg.

5

P450

200-800mg

P450

CYP1A2 CYP3A CYP2D6

CYP2C9

CYP3A -

60mg

12

CYP3A4

5mg

AUC 15%

CYP3A

CYP2D6 -

40 60mg

13

CYP2D6

50mg

CYP2D6

,

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
2.0mg/kg/ ADHD				1.6mg/kg/ ADHDRS	
	12	12	17		
-	6-15				ADHD
1.2-1.8mg/kg/ CGI-ADHD-S	10			4 N=292	DSM-IV ADHD N=124
25%				ADHDRS-IV-Parent	
N=81	N=82			8	CGI-ADHD-S
2		ADHDRS-IV-Parent			90%
2	DSM-IV	ADHD	18		
		ADHD			
	30			CAARS	ADHD
18	ADHD	CAARS	/		
		intent-to-treat			
2	10			5 N=280	6 N=256
					60
120mg/					95mg/

CAARS

ADHD

<42

/

ADHD

Ames

CHO

DNA

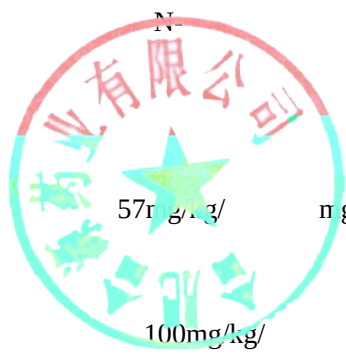
UDS

CHO

Ames

UDS

N



57mg/kg/

mg/m²

6

100mg/kg/

3

1

30mg/kg/

mg/m²

100mg/kg

23

AUC

AUC

3.3

0.4

50mg/kg/

mg/m²

6

2

10

2

1

25mg/kg

13mg/kg

2

10

40mg/kg/

mg/m²

5

20mg/kg/

150mg/kg/

mg/m²

17

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 10 50mg/kg

10 50mg/kg 50mg/kg 50mg/kg

15 10 50mg/kg 50mg/kg 30 50mg/kg

60

CYP2D6 P450 2D6

PM CYP2D6 PM

1% 7% 2% [EM] 10

AUC 5 24 CYP2D6

400 mg/kg

Cmax AUC

1-2 EM PM 63% 94%

Cmax

AUC Cmax 37% Tmax 3

Cmax 9%

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 PM 45%

EM 0.35L/hr/kg 5.2

PM 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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