

2021 10 26

2021 12 30

合源® 思源清®

/ ADHD

ADHD

/

12

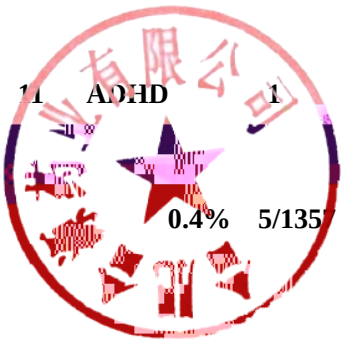
2200

11

ADHD

1

6 18

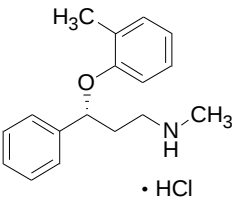


851

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

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

a 2%

2%

b

c

d

e

f

g



STRATTERA N=543

N=869

STRATTERA N=754

N=691

		2%		CYP2D6		PM			PM	
CYP2D6		EM				PM	4%	EM	1%	PM
	35%	EM	17%		PM	11%	EM	7%		PM
		PM						PM	5%, EM	2%
		PM	23%	EM	15%		PM	5%	EM	1%
									PM	19%, EM
	11%			PM	7%, EM	3%		PM	5%	EM
										3%
	PM	3%	EM	1%		PM	6%, EM	1%		PM
										21%,
EM	9%			PM	6%, EM	2%		PM	15%	EM
										7%
	PM	3%	EM	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

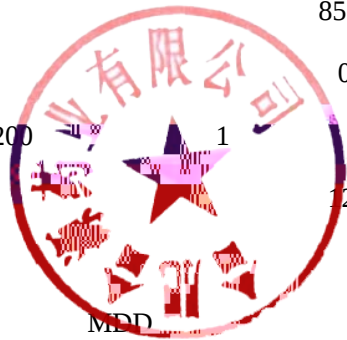
2200

1

2

ADHD

MDD



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% 5/1597

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% 0.39-4.98-

]

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		

 β_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
/

DSM-IV ADHD intent-to-treat ADHDRS

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	DSM-IV ADHD
				N=292		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 ≥42

/ ADHD

Ames

CHO

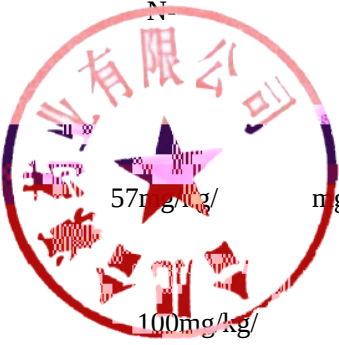
DNA

UDS

CHO

Ames

UDS



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

CYP2D6 4-

4-

EM 1% PM 0.1% 4- CYP2D6

PM 4- P450 N-

CYP2C19 P450

EM

EM

PM

PM

N-

34 40

4- -O- 80%

17%

3%

50% PM 45%

0.35L/hr/kg 5.2

0.03L/hr/kg 21.6 EM

AUC 10 C_{ss} C_{max} 5 EM 4-

6 8 PM N-

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

24

YBH12472021

H20213814

358

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