

2021 10 26

2021 12 30

合源® 思源清®

/ ADHD

ADHD

/

6

18

12

2200

11 ADHD

1

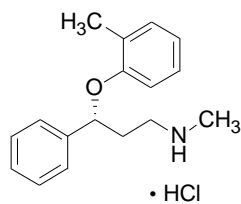
0.4% 5/1357

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( 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% x i, . ± V õ o 1 U 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

---

:

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%

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/                 |
| $\pm 0.29\text{mg/kg/}$ |        |           |       |           | 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 <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

/ 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

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