

| | | |
|------|----|----|
| 2009 | 04 | 16 |
| 2010 | 01 | 21 |
| 2011 | 07 | 18 |
| 2013 | 05 | 15 |
| 2014 | 02 | 18 |
| 2014 | 06 | 16 |
| 2014 | 07 | 17 |
| 2014 | 09 | 29 |
| 2015 | 12 | 24 |

请仔细阅读说明书并在医师指导下使用。

警示语

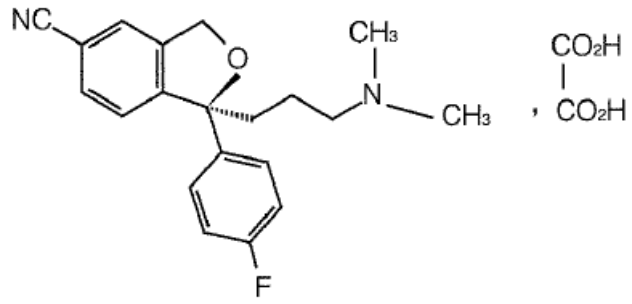
自杀倾向和抗抑郁药物

对抑郁症（MDD）和其他精神障碍的短期临床试验结果显示，与安慰剂相比，抗抑郁药物增加了儿童、青少年和青年（<24岁）患者自杀观念和实施自杀行为（自杀倾向）的风险。任何人如果考虑将本品或其他抗抑郁药物用于儿童、青少年或青年（<24岁），都必须权衡临床需求和风险。短期临床试验没有显示出，与安慰剂相比年龄大于24岁的成年人使用抗抑郁药物会增加自杀倾向的风险；在年龄65岁及以上的成年人中，使用抗抑郁药物使自杀倾向的风险有所降低。抑郁和某些精神障碍本身与自杀风险的增加有关，必须密切观察和合理监测所有年龄患者使用抗抑郁药物治疗开始后的临床症状的恶化、自杀倾向、行为的异常变化。应建议家属和看护者必须密切观察并与医生进行沟通。本品未被批准用于儿童患者（见【警告】、【注意事项】和【儿童用药】）。

Escitalopram Oxalate Tablets

Caosuan Aisixitaipulan Pian

S (+)-1-(3-)-1-(4-)-1,3- -5-



$C_{20}H_{21}FN_2O \cdot C_2H_2O_4$

414.43

400

20 mg

10mg
 1 2 4 6
 20mg

5mg 10mg
 1 20mg
 3

>65
 5mg 10mg

<18
 18

CL_{CR}<30ml/

10mg

5mg 2

P450 2C19 CYP2C19

CYP2C19

5mg 2

10mg

1 2

20mg

1 2

SSRI

≥1/10 ≥1/100 <1/10 ≥1/1,000 <1/100 ≥1/10,000
<1/1,000 <1/10,000

| 系统器官分类 | 发生率 | 不良反应 |
|--------|-----|------|
| | | |
| | | |
| | | |
| | | |
| | | 2 |
| | | |
| | | |
| | | |

| | | |
|--|----|-----|
| | | 1 |
| | | |
| | | |
| | 5- | |
| | | 2 / |
| | | |
| | | |
| | | |
| | | QT |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

1.

2. SSRI

50

50

SSRIs

TCA_s

QT

QT-
QT

QT

SSRI

SSRI/5

-

SNRI

/

1.

2.

MAOI

3.

4.

5.

QT

QT

1.

meta

25

2. QT

QT

QT

QT

ECG

ECG

ECG

3.

MAOIs

MAOIs

MAOIs

SSRIs

SSRIs

MAOIs

MAOIs

MAOIs 14

14

MAOIs

4. 5-

NMS

SNRIs SSRIs

5-

5-

MAOIs

5-

NMS

5-

/

5-

5-

MAOIs

5-

5-

5-

1.

SNRIs SSRIs

2.

SSRIs

/

SSRIs

3.

SSRI

SIADH

4.

/

SSRIs/SNRIs

5.

6.

7.

SSRI

/

8. ECT

SSRIs ECT

9.

10.

11.

12.

/

SSRI/SNRI

5-

SSRI

<24

SSRI

PPHN

1000

SSRI

5

1000

1

2

PPHN

18

18

65

5mg

10mg

5-

MAOIs

SSRI

MAOI

SSRI

MAOI

5-

MAOIs

MAOI

14

7

MAOI

40mg

2mg

AUC

QTc

10

MAO-A

5-

MAO-A

MAOI

1

[

B (MAO-B)

]

5-

5-_____

5-

5-

SSRI

SSRI

SSRI

SSRI

SSRI

CYP2D6

CYP2C19

CYP3A4

CYP2D6

CYP2C19

50%

70%

CYP2C19

CYP2D6

CYP2D6

CYP2D6

CYP2D6

CYP2C19

CYP2C19

600mg

400 800mg

5-

QT-

/

4

8

3

10mg

20mg

8

20mg

40mg

20mg

10mg

24

10mg

20mg

10 20mg/ 8

274

36 36

10 5 20mg/
 10 40mg/

(≥5%)

3 12 1 6
 24 5mg 10mg 20mg

20mg/ 20mg/
 5mg/ 10mg/

2

(P≤ 0.05)

670 341
 58.1% 40.2% CGI-I 1 2 24.8% 12.9%(CGI-S 1 2)

(P≤0.001)

4 10mg 20mg/
 5mg/

3 8 421
 419 47.5% 28.9 % CGI-I 1 2

37.1% 20.8%(CGI-S 1 2) (P≤0.001)

4 12 10mg/
 20mg/ 5mg

10mg 20mg/ (P≤0.01)

12 373 24 76
 20mg/

| | | | | | | | | |
|--------|-------------------|---------------------|-----------|---|------------------|------------------|------------------|----------------------------------|
| | | | | | S- | | | |
| | | | | | 5-HT | | | 5- |
| | | | | | | | | SSRI |
| | | | | | 5-HT | | | |
| R- | 100 | | | | 5 | | | |
| | | 5-HT ₁₋₇ | α | β | D ₁₋₅ | H ₁₋₃ | M ₁₋₅ | |
| | | | | | | Na ⁺ | K ⁺ | Cl ⁻ Ca ²⁺ |
| <hr/> | | | | | | | | |
| | Ames | | | | 5 | | 2 | TA98 |
| TA1537 | | | CHL | | | | | |
| | | | | | | | HPRT | |
| | DNA | | UDS | | | | | |
| <hr/> | | | | | | | | |
| | | | | | 32 | 48 | 72mg/kg/ | |
| | | | | | | | 48mg/kg/ | |
| | | | | | | | 56 | 112 |
| | | | | | | | 150mg/kg/ | |
| [| mg/m ² | | | | (MRHD)20mg/ | | ≥56 |] |
| | | | | | | | | |
| | | | | | | | MRHD | 28 |
| | | | | | 6 | 12 | 24 | 48mg/kg/ |
| 24 | | | | | | | | MRHD |
| | | | | | | | | |
| | | | | | | | 24mg/kg/ | |
| | 12mg/kg/ | | MRHD | 6 | | | | |
| | | | | | | | / | |
| | | | | | | | / | |
| | | | | | | | / | |
| | 32 | 56 | 112mg/kg/ | | | | | |

56mg/kg/ 16mg/kg/
 4.8 12.8 32mg/kg/
 4 12.8mg/kg/
 NMRI/BOM COBS WI 18 24
 240mg/kg/ 8 24mg/kg/
 4
 80%
 V_{d,β}/F 12 26L/kg
 80%
 N N
 28% 31% <5% P450 CYP 2C19
 CYP3A4 CYP2D6
 30 CL_{oral} 0.6 L/
 10mg
 50nmol/L 20 125nmol/L
 >65
 AUC 50%
 (Child-Pugh A B)
 2 60%

CL_{CR}

10 53ml/

CYP2C19

CYP2D6

30

7 / 14 /

36

JX20090196

H20140121

J20140079

H. Lundbeck A/S

Ottiliavej 9 DK-2500 Valby Denmark

34

710043

400 888 9988

029 82576616

<http://www.xian-janssen.com.cn>