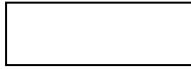
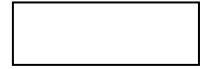


2022 12 30

2023 1 16



# 盐酸达泊西汀片说明书



Dapoxetine Hydrochloride Tablets

Yansuan Daboxiting Pian

(+)-(S)-N N- -( )-[2-(1- ) ]-

$C_{21}H_{23}NO \cdot HCl$

341.88



18 64

PE

IELT

2

PE

6

C<sub>21</sub>H<sub>23</sub>NO 1 30mg 2 60mg

18 64

60mg

30mg

1 3

30mg

60mg

60mg

24

4

6

-

24

65

65

18

Child-Pugh C

CYP2D6

CYP2D6

CYP 2D6

CYP 2D6

60mg

CYP3A4

CYP3A4

CYP3A4

30mg

---

3 (30mg 60mg  
 11.0% 22.2%) (5.8% 10.9%) (5.6% 8.8%)  
 (3.5% 6.9%) (2.1% 3.9%) (2.0% 4.1%)  
 2.2% 1.2%

---

4224  
 4224 1616 30mg 2608 60mg  
 1

**1** MedDRA

	(> 1/10)	< 1/10)	< 1/100)	< 1/1000)


9

---

Holter

3

3

0.06% 30mg

0.23% 60mg

3

1 PE

0.64%

---

CYP2D6

60mg

CYP2D6

60mg

---

5-

SSRI

62

[

5-

24

C-CASA

---

/

Holter

3

3

CNS

---

recreational drugs

5-

5-

---

---

---

P450 3A4

P450 3A4

30mg

---

P450 2D6

P450 2D6

P450 2D6

60mg

---

/

---

5-

---

18

18

---

5-

---

5-

[NSAID]

\_\_\_\_\_

\_\_\_\_\_

5-

60mg

62

24 30mg 60mg

1

\_\_\_\_\_

5-

\_\_\_\_\_

Lapp

-

\_\_\_\_\_

100mg/kg

75mg/kg

C<sub>max</sub> AUC<sub>inf</sub> T<sub>max</sub>

---

---

5- MAOI

5-

5-

14 7

---

QTc

P450 2D6

QTc

14 7

---

5- /

5- 5- /

L- 5-

5- -

5- 5-

5- / / 14

7 /

---

CNS

---

---

P450

2D6 P450 3A4 1 FMO1





240mg 120mg 3

5-

5-

5- SSRI IC<sub>50</sub> 1.12nM  
IC<sub>50</sub> 1.0nM IC<sub>50</sub>=2.0nM  
IC<sub>50</sub>=282nM

5-

LPGi

Ames

tk

2

225mg/kg/

60mg 2

Tg.rasH2 6

100mg/kg

60mg

4

200mg/kg

1-2

C<sub>max</sub>

42%

15-76%

30mg

60mg

1.01 1.27 297ng/ml 498ng/ml  
C<sub>max</sub> 10% AUC 12%

99%  
98.5% 162 L  
0.10 2.19 19.3

2D6 P450 3A4 1 FMO1 <sup>14</sup>C- P450

N N

-N-

50%

24

5%

19

60mg

AUC

10% 20%

65

60mg

C<sub>max</sub> AUC<sub>inf</sub> T<sub>max</sub>

60mg



88

510515

020 87063679

020 87573176

020 87062636

020-87061075

<http://www.byszc.com>

88

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