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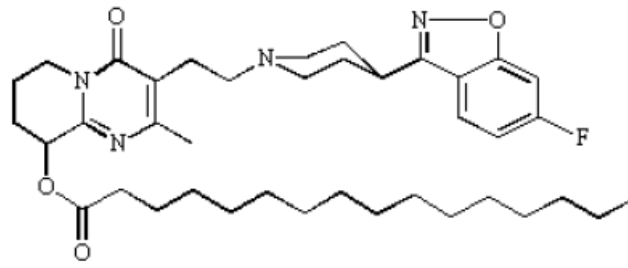
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	2	1	<1	0	1	1
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	0	1	<1	1	1	2
	4	4	1	1	1	2
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	1	<1	<1	1	1	2
1	2	1	<1	1	0	2
1	0	2	2	2	3	0

	3	2	2	3	1	5	6
	1	6	2	4	1	4	2
	1	5	2	3	1	0	0
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a

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150mg 4 25 mg 100 mg 150 mg 25

mg 50 mg 100 mg

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EPS

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Simpson-Angus

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MedDRA

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FI	10	12	11	11
	5	6	6	4
	2	2	2	4
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9

7% 4% 18% 11% 50 mg 100 mg 9% 5%

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mg 10.3-7.7 50 mg 10.0-9.2 100 mg 11.1-8.8 9

10.9-9.8 25

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DC I

DC I

DC I

QTc QTc
IA III
QTc QT
QTc /
1 2 3 QTc
4

400 mg
6

QT n = 141
QTcLD

150mg

QT

2

QT

8 mg

12.3 msec (90% CI: 8.9

$C_{max ss} = 113$ ng/mL

$C_{max ss} = 50$ ng/mL

n=50

15.6)

8

1.5

8 mg

/

4 mg $C_{max ss}=35$ ng/mL 2 1.5 QTcLD
6.8 msec 90% CI: 3.6 10.1

ECG 12 mg 6
60 msec 62 msec

GJYB: 4 + c i[Y GJYB: , c i[Y
GJYB: + - c i[Y 8 W[GJYB: GJYB:
, c i[Y GJYB: *.) c i[Y
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7 4 1
 9 3 13

- * /)

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c]%B						
a	150mg	4		25 mg	100 mg	150 mg
mg	50 mg	100 mg				25

c] +
 +) d3 , . c]%B (/ d3 / * c]%B

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	(+c]	+ c]	c]	+ % ₀ + c] ^w	+ % c] ^w	+ % ₀ + c] ^w
	c]%ZB					
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c]%B

a 150mg 4 25 mg 100mg 150 mg 25
mg 50 mg 100 mg

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7% 10
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	*	*	.	*	*	-

-)) , . / / +. .))

^a 150mg 4 25 mg 100mg 150 mg 25
 mg 50 mg 100 mg

(*a] d3)* *)a] d3) + c] (/ +)

D₂

GnRH

PSY-3001

>30 ng/mL 50.5% vs. 42.9% 51.9% vs. 29.0% >18 ng/mL

N=2 N=1 N=1 N=1 4.2 2

1 2.2 0.9 1 0.9

N=358 N=470 SD N=333 N=490

24.7 22.5 ng/mL 59.5 38.1 ng/mL 14.9 22.3 ng/mL 35.2 39.6 ng/mL

49.2% 47.7%

5.3% vs. 1.8% 2.5

2%

4 - 25mg-150 mg

/

<1% 2/1293 4 <1% 4/1293 0% 0/510
0% 0/510

/
ANC / WBC/ANC / WBC /
WBC CBC /
WBC
<1000/mm³

-

/

126

2-4% 15-20%

/ /

%

%

/

%

6

Medicaid

9258

1566
95 CI 0.88-1.81

RR=1.26 95 CI 1.02-1.56

RR=1.26

126

D₂

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11

	9DI 9DI	
9OF)7* F]] 9OF)7* F	% F] 9OF)7*

F*+

9 OF(: , 9 OF) 7*

9 OF 7(9 OF) 7,

9 OF) 9/ 9 OF) 9 /

405 mg

QT 1

IV DSM-IV

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64

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PANSS

F7 DII

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F7 DII * F7 DII

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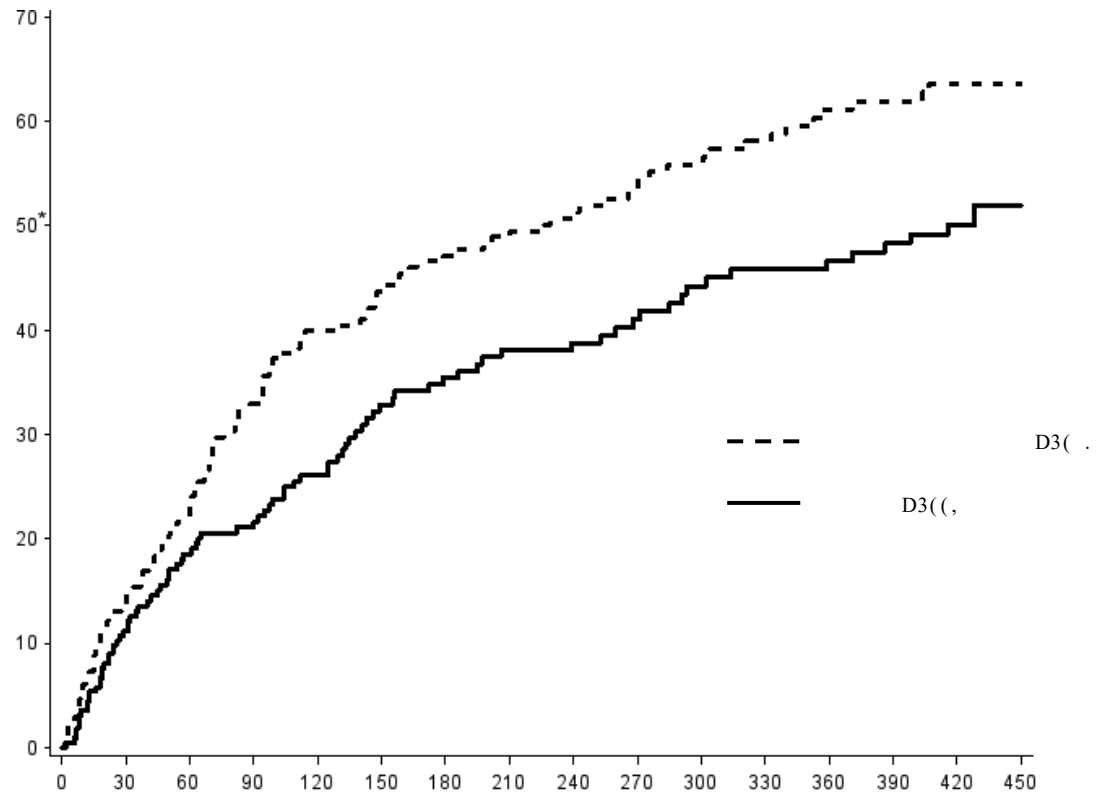
226

Kaplan-Meier

2

13

/



*

416

226

2

Kaplan-Meier

6

/

	N=226 %	N=218 %	^a [95% CI]
	90 39.8%	117 53.7%	0.70 [0.53 0.92]
▪ /	48 21.2%	64 29.4%	
▪	18 8.0%	26 11.9%	
▪	15 6.6%	8 3.7%	
▪	5 2.2%	6 2.8%	
▪	3 1.3%	4 1.8%	
▪	1 0.4%	9 4.1%	
▪	0	0	
/ ^b	76 33.6%	98 45.0%	0.70 [0.52 0.94]

^a Cox

^b

+ (+>J₍₇ 察 (: (
 D₂ 5HT_{2A} (> (+ (+>J₍₇
 Ki 1.6~2.8 nM 0.8~1.2 nM
 Ames 服 Ames

服

服

2.5 mg/kg/ [mg/m² 服

MRHD 12 mg/ 2]

0.63 mg/kg/ 到 mg/m² MRHD 服

2.5 mg/kg/ 服

[0.31~5.0 mg/kg/ mg/m² 8 [Wt]

MRHD 10 mg/ 1.0~16]

不

1 不 250 mg/kg

服 1 不 MRHD 150

mg 10 mg/m⁽

8 mg/m⁽ 服 MRHD 12 mg/

MRHD 10 mg 4.8~6.4 mg/m² MRHD

6.4 - MRHD

10 mg/ 9.6 mg/m² MRHD

1.0 MRHD 0.8~1.9 mg/m²

MRHD mg/m²

D₂
服

服

1 不

24

73

0.63 mg/kg/

2.5 mg/kg/

AUC

12 mg/

AUC
2~3

服

40

0.31

1.25

5 mg/kg/

AUC

0.31 mg/kg/
MRHD 6 mg/
12

AUC

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服

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J_{c w}

(+ + c] 9_{c w}

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9OF(: , 9OF)7*

9OF(: ,

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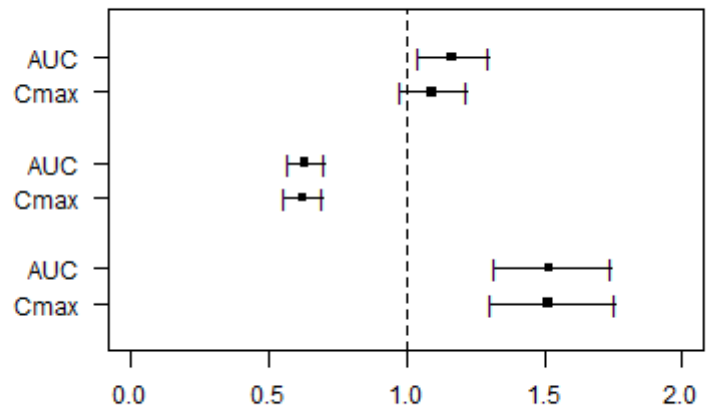
),

9OF(: ,

9_c w 7 K9) (c]%

) 9OF)7* F

9_c w 7 K9)+



3

9_{c w} 7 K9 + 500 mg 1 2
)
) + c]%
 9OF(: , 9OF)7*
 F F]

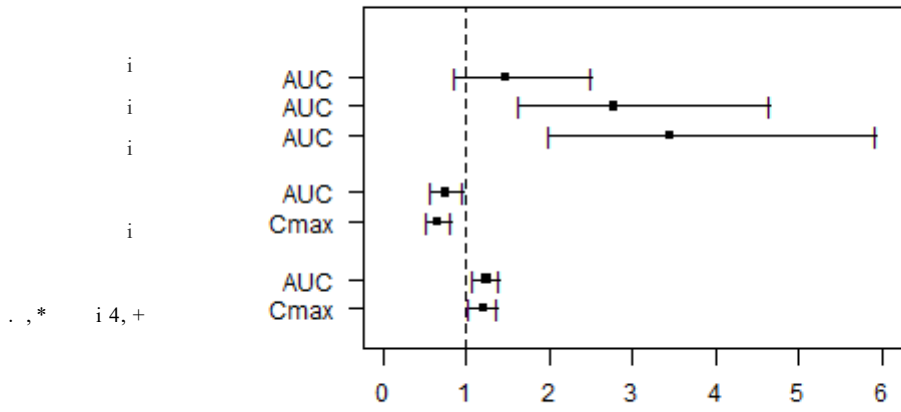
CYP3A4 CYP3A5 CYP1A2 CYP2A6 CYP2C8/9/10 CYP2D6 CYP2E1 P450

P-gp

4

9 c w 7 K9

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CYP1A2

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c b c]	0>(, ,*(
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J hd e i[[]) 8 ()* 8[[hi[8[b] c

Wii[d F Wc W[YWDL

J hd e i[[]) 8 ()* 8[[hi[8[b] c

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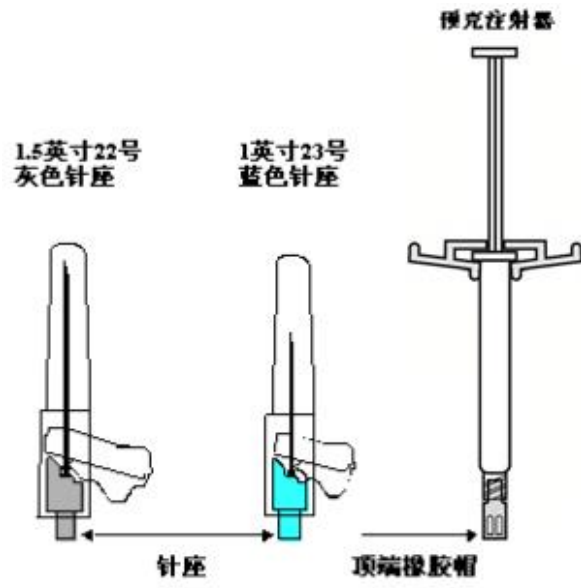
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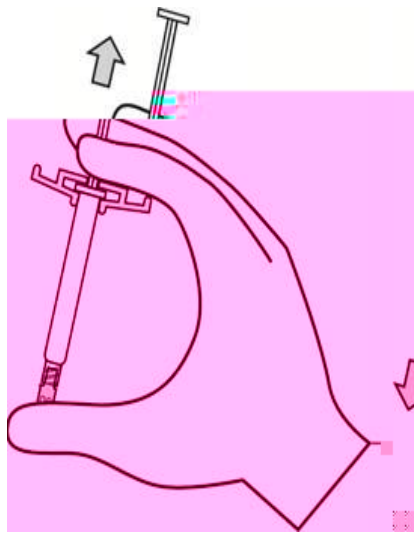
0% W Wii[d Yec Yd

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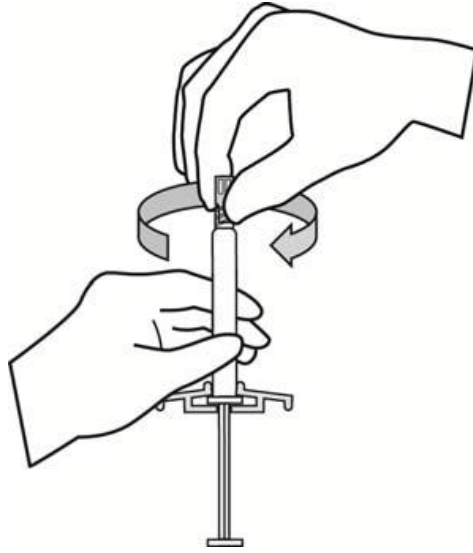
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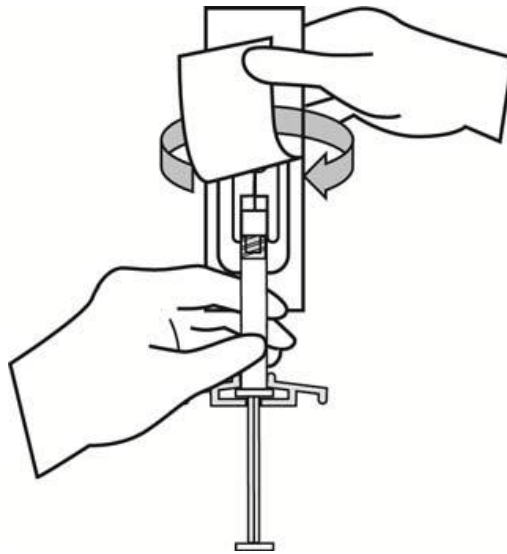
• (/ a] + ((

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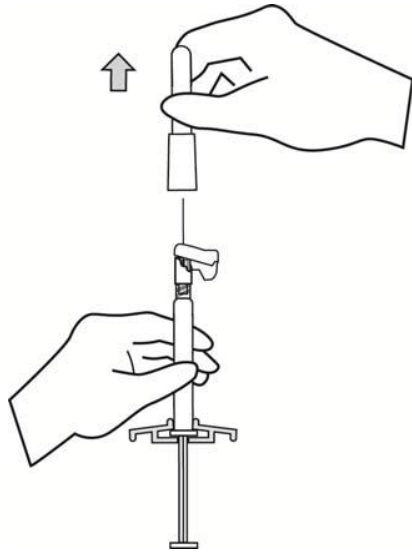
3.



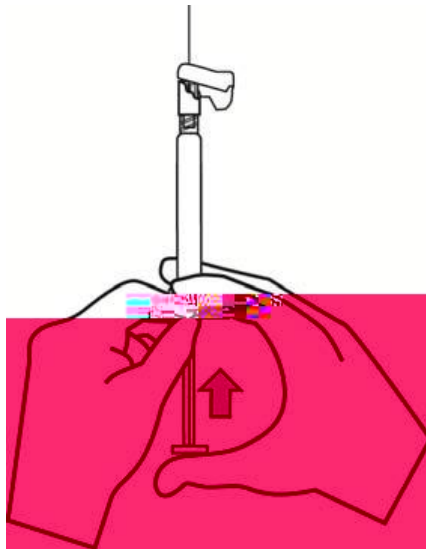
4.



5.



6.



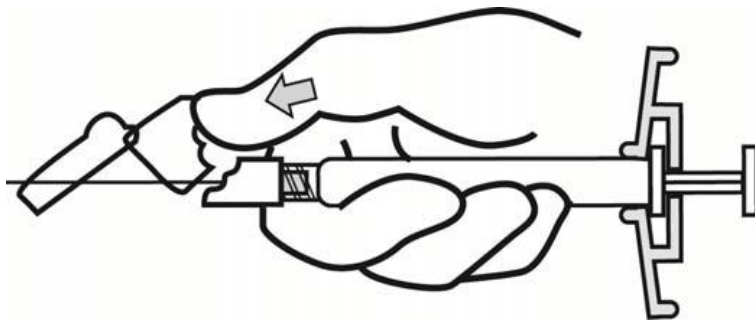
7.

8.

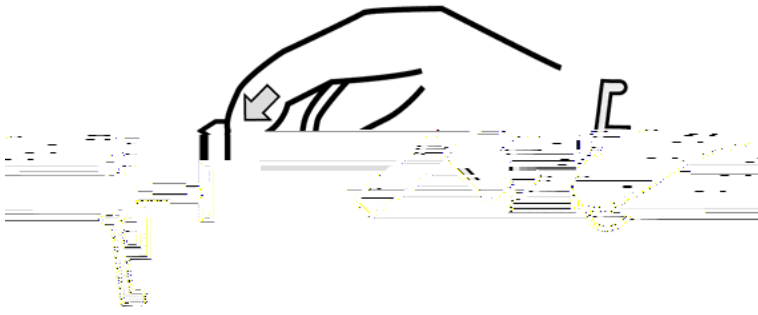
. W . X

. Y

. W



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