

/OUVIVIO
Daridorexant Hydrochloride Tablets
Yansuan Dalileisheng Pian



K 30

25mg 25 Idorsia
50mg 50 Idorsia



7 25mg 50mg 30

CYP3A4 CYP3A4

CYP3A4
CYP3A4
CYP3A4 25mg
CYP3A4

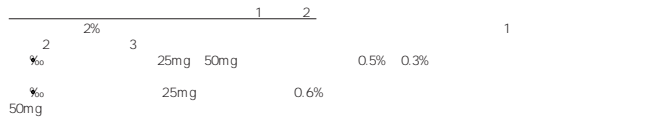
Child-Pugh 7-9 25mg
Child-Pugh 10

3 2 3 [1 2] 1 9 [3]
10mg 1 50mg 25mg 25mg 10mg
50mg N 308 25mg N 618 10mg 1847 [65]
6 N 306 N=615 576

1 1 2% 5%

	25mg N 310 %	50mg N 308 %	N 309 %
*	6	7	5
*	6	5	4
*	2	3	2
*	0	3	2

*



1
CNS
50mg
CNS
CNS
CNS
CNS

2 /

2

CYP3A4	
	CYP3A4
	CYP3A4 25mg
	CYP3A4
CYP3A4	
	CYP3A4
	CYP3A4
	/

AUC 25mg O GMR 90% CI PK C_{max} GMR PK

CYP3A4 AUC 50% Cmax GMR 90% CI 0.6g/L 5h 25mg 400% CI 90% CI SSRI 5- PK PBPK CYP3A4 AUC 50mg CI

AUC P-gp P- SSRI BCRP 5- 3 CI C_{max} CYP P450

1 [NCT03545191] 2 [NCT03575104]

1854 3 5 (DSM+5-) 930 50mg N 310 25 924 25mg N 309 10mg N 307 3

3 NCT03679884 1 55.4 18.88 39.1% 65 5.8% (67.1%) 75 (90%)

(8%) (1.0%) 1%

2 56.7 19.85 39.3% 65 6.1% (69.0%) 75 (88%)

(8%) (4%) 1% 3

1 LPS 3 (LPS) WASO (sTST) (IDSIO) (WASO)

[SD] / 1 25 50mg 1 3 LPS WASO

1 50mg (sTST) 4 3 IDSIO

2 50mg 1 25 mg 1 3 WASO sTST

5 10mg 1 3 LPS WASO sTST

4 1 3

/ N	(SD)	1		3		
		(SD)	LSM (95% CL)	LSM (95% CL)	(SD)	LSM (95% CL)
WASO		min		PSG		
50 mg (310)						
LPS		min		PSG		
50 mg (310)						
25 mg (310)			316			
(310)	67 (40)	46 (36)	(53, 20) [-23, 6]	38	5/ 61	0
sTST		min		PSG		
50 mg (310)	313 (58)	358 (74)	[44, 57] [31, 49]	60	372 (79)	58 [51, 64]
25 mg (310)	310 (60)	345 (66)	[34, 57] [29, 40]	31	372 (72)	48 [41, 54]
(310)	316 (53)	338 (65)	[22, 35] [16, 27]	22	354 (73)	38 [31, 44]
IDSIO		min		PSG		
50 mg 310	22.5 (7.2)	18.6 (7.8)	-3.8 [-4.3, -3.2]	-1.8* [-2.5, -1.0]	16.5 (8.1)	-5.7 [-6.4, -5.0]
25 mg 310	22.1 (6.9)	19.4 (7.1)	-2.8 [-3.3, -2.2]	-0.8 [-1.5, 0.0]	17.3 (7.6)	-4.8 [-5.5, -4.1]
(310)	22.3 (6.9)	20.3 (6.9)	-2.0 [-2.6, -1.5]		18.5 (7.8)	-3.8 [-4.5, -3.1]

* CL WASO LPS LSM IDSIO= PSG SD sTST

p 0.05

5 2 1 3

/ N	(SD)	1		3		
		(SD)	LSM (95% CL)	LSM (95% CL)	(SD)	LSM (95% CL)
WASO		min		PSG		
25 mg (309)	106 (49)	80 (44)	-24 [-28, -20]	-12* [-18, -6]	80 (49)	-24 [-29, -19]
(308)	108 (49)	93 (50)	-13 [-17, -8]		91 (47)	-14 [-19, -9]
LPS		min		PSG		
25 mg (309)	69 (41)	42 (39)	-26 [-31, -22]	-6 [-12, -1]	39 (37)	-29 [-33, -24]
(308)	72 (46)	50 (40)	-20 [-24, -16]		49 (46)	-20 [-24, -15]
sTST		min		PSG		
25 mg (309)	308 (53)	353 (67)	44 [38, 49]	16* [8, 24]	365 (70)	56 [50, 63]
(308)	308 (52)	336 (63)	28 [22, 33]		347 (65)	37 [31, 43]
IDSIO		min		PSG		
25 mg (309)	22.2 (6.2)	18.7 (6.5)	-3.5 [-4.1, -2.9]	-0.8 [-1.6, 0.1]	17.0 (7.0)	-5.3 [-6.0, -4.6]
(308)	22.6 (5.8)	19.8 (6.3)	-2.8 [-3.3, -2.2]		18.4 (6.6)	-4.0 [-4.7, -3.3]

4 sTST 1