

/QUVIVIQ
Daridorexant Hydrochloride Tablets
Yansuan Dalileisheng Pian

(S)-(2-(5- -4- -1H- [d] -2-)-2- -1-)(5- -2-(2H-1,2,3- -2-)

)

C₂₃H₂₃ClN₀O₂·HCl
487.38

K30

25mg " 25 " Idorsia " "
50mg " 50 " Idorsia " "

C₂₃H₂₃ClN₀O₂ 1 25mg 2 50mg

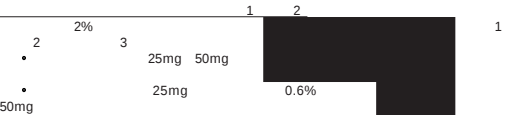
25mg 50mg 30

CYP3A4 CYP3A4
CYP3A4 CYP3A4
CYP3A4 CYP3A4 25mg
CYP3A4 CYP3A4
Child-Pugh 7-9 25mg
Child-Pugh ≥ 10

3 2 3 [1 2] 1 9 [3]
10mg 1 50mg 25mg 1847 40% 2 25mg 10mg
50mg N 308 25mg N 618 10mg 12 N 306 N=615 576
6
1 1 2% 5%

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

*



1]
1 CNS
CNS 50mg
CNS CNS
2 /

CYP3A4	
	CYP3A4
	CYP3A4 25 mg
	CYP3A4
CYP3A4	
	CYP3A4
	CYP3A4
	/

AUC 25mg 0 GMR 90%CI PK CI C_{max} GMR PK

2 3

CYP3A4 AUC Cmax 50% 0.6g/L 5h 2 25mg PK 400% 90% CI 50mg PBPK CYP3A4 AUC CI

AUC P_{gp} P SSRI BCRP 3 CI C_{max} PK CYP P450

1 [NCT03545191] 2 [NCT03575104]

1854 3 5 (DSM-5®) 50mg N 310 25 mg N 307 3 N 308 10mg 7 9 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) WASO (sTST) (IDSIQ) 1 [SDQ] IDSIQ / 25 50mg 1 3 LPS WASO (sTST) IDSIQ 2 50mg 5 10mg 1 25 mg 3 1 3 WASO sTST

4 1 1 3

/ N		1		3		
	(SD)	(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)						
(310)	67 (40)	46 (36)	-20 [-23,			
sTST min						
50 mg (310)	313 (58)	358 (74)	44 [38, 49]	22* [14, 30]	372 (79)	58 [51, 64]
25 mg (310)	310 (60)	345 (66)	34 [29, 40]	13* [5, 20]	358 (72)	48 [41, 54]
(310)	316 (53)	338 (65)	22 [16, 27]		354 (73)	38 [31, 44]
IDSIQ						
50mg 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]
25mg 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 IDSIQ= p 0.05 PSG SD sTST

5 2 1 3

/ N		1		3		
	(SD)	(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						
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]
IDSIQ						
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