2025 06 17
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k

/QUVIVIQ
Daridorexant Hydrochloride Tablets
Yansuan Dalileisheng Pian

k

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

$C_{23}H_{23}ClN_6O_2$´ HCl
487.38
! ! K30 ! ! ! ! k

25mg 25 Idorsia k
50mg 50 Idorsia k

/ k

$C_{23}H_{23}ClN_6O_2$ 1 25mg 2 50mg

25mg 50mg 30
7 k
β γ k

CYP3A4 CYP3A4
CYP3A4
CYP3A4 β γβ γ k
CYP3A4
CYP3A4 25mg β γβ
γ k
CYP3A4
CYP3A4 β γ k

Child-Pugh 7-9 25mg β γ k
Child-Pugh ≥ 10 k

k
3 2 3 [1 2] 1 9 [3]
k 1 50mg 25mg 2 25mg 10mg
k10mg k 1847 40% [≥ 65]
50mg N 308 25mg N 618 10mg N 306 N=615 k 576
6 331 12 k

1 5% k
1 1 2% k

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

*
! ! ! !
! ! ! !
! !
! !
1 2
2% k 1
2 3 k
• 25mg 50mg 0.5% 0.3%
k
• 25mg 0.6%
50mg k

! !
k
k [β
γ] k

1
CNS k
CNS k k
50mg k
β γ k
k
CNS ! ! ! CNS
CNS k CNS CNS
k k
k
k

2 /
CNS Ů τ ж

CYP3A4	
	CYP3A4 β γ k
	CYP3A4 25 mg β γ k CYP3A4 β γ k
CYP3A4	
	CYP3A4 β γ k
	CYP3A4 β γ k
	β γ k
	β γ k k / β γ k

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

2 3

2 PK

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

3 PK

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

1 [NCT03545191] 2 [NCT03575104]

1854 5 (DSM-5)
3 1 930 50mg N 310 /25
mg N 310 N 310 2 924 25mg N 309 10mg
N 307 N 308 10mg
3 7 9
3 NCT03679884
1 55.4 18-88 39.1% ≥ 65 5.8% ≥ 75
(67.1%) (90%)
(8%) (1.0%) 1%

2 56.7 19-85 39.3% ≥ 65 6.1% ≥ 75
(69.0%) (88%)
(8%) (4%) 1%
1 3 (LPS) (WASO)
LPS WASO
I (sTST)
[SDQ] (IDSIQ)
IDSIQ /
1 25 50mg 1 3 LPS WASO
(sTST) 4 IDSIQ
50mg
2 25 mg 1 3 WASO sTST
5 10mg 1 3 LPS WASO sTST

4 1 3
1

/ N		1			3		
	(SD)	(SD)	LSM (95% CL)	LSM (95% CL)	(SD)	LSM (95% CL)	LSM (95% CL)
WASO		**min**		**PSG**			
50 mg (310)							
LPS		**min**		**PSG**			
50 mg (310)							
25 mg (310)							
(310)	67 (40)	46 (36)	35 -20 [-23, -129]	10*			
sTST		**min**					
50 mg (310)	313 (58)	358 (74)	44 [38, 49]	22* [14, 30]	372 (79)	58 [51, 64]	20* [11, 29]
25 mg (310)	310 (60)	345 (66)	34 [29, 40]	13* [5, 20]	358 (72)	48 [41, 54]	10* [1, 19]
(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]	-1.9 * [-2.9,-0.9]
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]	-1.0 [-2.0,0.0]
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]	

p 0.05
CL LPS LSM PSG SD sTST
WASO IDSIQ=

5 1 3
2

/ N		1			3		
	(SD)	(SD)	LSM (95% CL)	LSM (95% CL)	(SD)	LSM (95% CL)	LSM (95% CL)
WASO		**min**		**PSG**			
25 mg (309)	106 (49)	80 (44)	-24 [-28, -20]	-12* [-18, -6]	80 (49)	-24 [-29, -19]	-10* [-17, -4]
(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]	-9 [-15, -3]
(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]	19* [10, 28]
(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]	-1.3 [-2.2, -0.3]
(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