2025 06 17
2025

/QUVIVIQ
Daridorexant Hydrochloride Tablets
Yansuan Dalileisheng Pian

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

$C_{23}H_{23}ClN_6O_2 \cdot HCl$
487.38

K30

25mg 25 Idorsia
50mg 50 Idorsia

/

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

25mg 50mg 30
7

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

1 5%
1 1 2%

	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% 1
2 3
25mg 50mg 0.5% 0.3%
25mg 0.6%
50mg

1

CNS CNS
CNS
50mg
CNS CNS CNS CNS CNS

2 **/**

CYP3A4	
	CYP3A4
	CYP3A4 25 mg CYP3A4
CYP3A4	
	CYP3A4
	CYP3A4
	/

25mg k GMR 90%CI k PK k

¼AUC 0 CI C_{max} GMR PK

k

2 k 3 k

2 PK

25mg 50mg k

0.6g/L 5h k PBPK

CYP3A4 AUC 400% k CYP3A4

AUC 50% k GMR 90% CI k 90% CI ¼AUC CI

Cmax GMR SSRI 5- k

3 PK

AUC BCRP CI C_{max} CYP P450

P-gp P- SSRI 5- k

! ! ! ! 1 [NCT03545191] 2 [NCT03575104]

k

1854 t u 5 (DSM-5®)

3 k 1 930 50mg N 310 /25

mg N 310 N 310 k 2 924 25mg N 309 ‘10mg

N 307 N 308 ¼10mg k 9 !

3 7

3 NCT03679884 k

1 55.4 18-88 39.1% ≥ 65 5.8% ≥ 75 k

k (67.1%) ! (90%) !

(8%) ! (1.0%) 1% k

2 56.7 19-85 39.3% ≥ 65 6.1% ≥ 75 k

k (69.0%) ! (88%) !

(8%) ! (4%) 1% k

1 3 (LPS) (WASO)

¼LPS WASO k

I (sTST)

[SDQ] k (IDSIQ) k

IDSIQ ! / k

1 25 50mg 1 3 LPS WASO

(sTST) 4 k IDSIQ

50mg k

2 25 mg 1 3 WASO sTST

5 k 10mg 1 3 LPS WASO sTST

k

! ! k

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)			[-23 H				
(310)	67 (40)	46 (36)	-20 [-23, (36)				
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]	17 !	354 (36 (73)	38 [31, 44]	35a (36)
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 k

CL LPS LSM PSG SD sTST

WASO IDSIQ=

5 1 3

2

10 ¼

/ 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]	

-ñ ¡ (46) [-26,) -1 ɣ˜

3 ñ ¡ (46 ę [-26,

-21˚ Ä (-1. o 4 e f

[-23 o -21˚ Ä (-1. o - ǔ ¡

35 ñ -21˚ Ä (-1.˝H (46)

(4) (310)

(310) (71, Ŝ

(40) ų

(40)- ǔ ,

(46)

4 e !

-21, Ä (-1.˝H

4 sTST 1

3 ñ 46 ˥

(36 ® (4 ®