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<br>N 310<br>% | 50 mg<br>N 308<br>% | N 309<br>% |
|---|---|---|---|
| | | | |
| * | 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** */*

2

***/*** ***x***

| **CYP3A4** | |
|---|---|
| | CYP3A4 |
| | CYP3A4 25 mg<br>CYP3A4 |
| **CYP3A4** | |
| | CYP3A4 |
| | CYP3A4 |
| | |
| | |
| | /<br> |

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
(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) | | | | | | | |
| | | | | | | | |
| | | | | | 27 40) | 35c | -23, / |
| **LPS** | | **min** | | **PSG** | | | |
| 50 mg (310) | | | | | | | |
| 25 mg (310) | | | (36) 46 (40) *17 316 | -0 (40) | 33 3œ | *-0 Ū | Ł Ð- |
| (310) | 67 (40) | 46 (36) | (310) 332 20 58 (36) -20 -23, 38 8 (36) 23, | | (9 *17 -0 *16 | *-0 6[5 | *336 ( |
| **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] | |

/ 17 58 -23, / -/ Ţ

**4** **sTST** **1**