

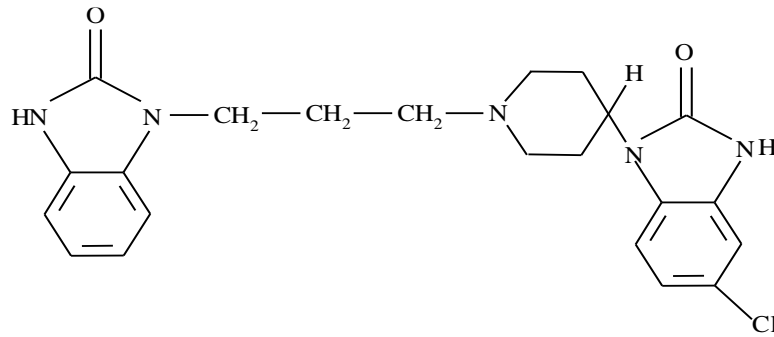
2007	03	13
2008	04	10
2011	12	14
2011	12	30
2012	09	06
2012	10	01
2014	01	23
2015	10	20
2016	12	28
2018	07	23
2019	01	01
2019	07	04
2020	05	15
2020	10	12
2023	01	17

®

Domperidone Tablets

Duopanlitong Pian

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



$C_{22}H_{24}ClN_5O_2$

425.91

:

K90

1.

-

-

-

-

2.

( )

10 mg

15~30

35 3 10 40  
 12 35 3  
 10

30 /  
 60

\_\_\_\_\_ 45 1221  
 15  
 553/1221

80mg 10mg~160mg 230 80mg 56  
 1~2248 45 1%

/	<b>n=1221</b> %
	2.5
	1.6
/	1.5
	5.6
	2.5

	1.0
	5.2
	2.8
	1.7
/	5.3
	4.4
	3.3
	2.9
	2.3
	2.0
	1.6
	1.9

45                      n=1221                      1%

/	<b>n=1221</b> <b>%</b>
	0.2
	0.7
	0.8
	0.5

\_\_\_\_\_

1/10  
1/100    1/10

1/ 1000    1/100  
1/10000    1/1000  
1/10000

	*

\*

/

1

•

•

•

( )

•

QTc

CYP3A4

•

1.

/

2.

3.

4.

1

35

12

35

5.

6.

60

30mg

QTc

7.

CYP3A4

CYP3A4

QT

CYP3A4

QT

QT

CYP3A4

QT

· IA

· III

·

·

- 
- 
- 
- 
- 
- 

8.

9.

10.

1

1

4

4

11.

1~2

12.

%

0.1%



1.  
2.  
3. CYP3A4  
CYP3A4  
CYP3A4  
\* \* \*  
\* \*  
HIV  
\*  
\*  
(\* QTc )  
4. CYP3A4  
· CYP3A4 C<sub>max</sub> 3  
· CYP3A4  
· QTc 10msec  
QTc CYP3A4

5.

/

CYP3A4

C<sub>max</sub> 3

10mg/	4	/	QTc	1.6msec	2.5msec	
200mg/	2	/	(500mg/	3	/ )	QTc 3.8msec
4.9msec			-			10mg/ 4
/		200mg/	2	/	QTc	9.8msec
QTc			1.2~17.5msec		-	
	10mg/	4	/	500mg/	3	/ QTc
	9.9msec		QTc		1.6~14.3msec	
				C <sub>max</sub>	AUC	3

6.

7.

•

•

( )

1.

-

2.

200mg/kg/

QTc

3. QT/QTc

ICH

E14

QT

10mg

20mg

4

QTc

LS-

3.4msec

20mg

4

4

90%CI

1.0~5.9msec

10msec

QT

20mg

40mg

4

5

QTc

5

1

t<sub>max</sub>

3

ECG

QTc

80mg

160mg

QTc

60  
91~93%  
7~9  
CYP3A4  
P450 N-  
CYP3A4 CYP1A2 CYP2E1 31%  
1% 66% 10%

Pugh 7~9 Child-Pugh B  
AUC C<sub>max</sub> 2.9 1.5 25  
15 23 C<sub>max</sub> AUC

6mg/100mL 0.6mmol/L  
7.4 20.8  
1%

2x21 / /

60

2020

H10910003

19

4 17F

19

710304

400 888 9988

(029) 82576616

<http://www.xian-janssen.com.cn>

**\*\*\*END OF DOCUMENT\*\*\***