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2006	09	12
2006	11	13
2007	03	28
2008	07	14
2010	03	25
2011	03	02
2011	04	29
2011	09	05
2013	12	09
2015	10	19
2015	11	07
2016	03	21
2016	05	18
2016	05	30
2016	07	05
2017	03	10
2017	09	25
2018	04	17
2019	03	25
2019	04	19
2019	06	13
2019	06	24
2020	04	07
2020	06	24

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/

P450 3A4

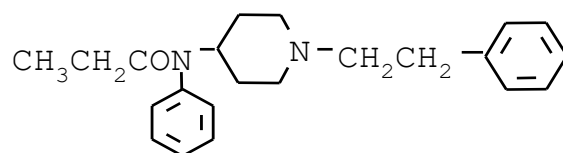
P4503A4

CYP3A4

Fentanyl Transdermal Patches

Fentaini Touptieji

N-[1-(2- )-4- ]-N- -



C<sub>22</sub>H<sub>28</sub>N<sub>2</sub>O

336.46

/ -

4            12 g/    <sup>1</sup> 2.1mg/  
              25 g/    4.2mg/  
              50 g/    8.4mg/  
              75 g/    12.6mg/

g/	cm <sup>2</sup>	mg
12.5	5.25	2.1
25	10.5	4.2
50	21	8.4
75	31.5	12.6

1

12.5 g/

---

---

25 g/

12 g/

25 g/

25 g/

---

1. 24
2. 1 1
3. 2 24  
10mg  
24
4. 12 g/ 25 g/

1

	mg	
	*	**
	10	30
	1.5	7.5
	10	20
	15	30
	2	4
	1	10
	5	60
	75	-
	130	200
	0.4	0.8
	100	120

\*

\*\*

/

Foley KM. NEJM1985; 313 (2): 84-95. N Engl J Med 1985;313(2):84-95 and McPherson ML.Introduction to opioid conversion calculations.In: Demystifying Opioid Conversion Calculations: A Guide for Effective Dosing.Bethesda, MD: American Society of Health-System Pharmacists; 2010:1-15.

2

\*

24	mg/24h	µg /h
<135		25
135~224		50
225~314		75

315~404	100
405~494	125
495~584	150
585~674	175
675~764	200
765~854	225
855~944	250
945~1034	275
1035~1124	300
*	

---

72 72 75 g/h 300 g/h	“ ”
48 72	
12 g/h 25 g/h 45/90 mg/ ≈ 12/25 g/h 6	2 72
“ ”	

\_\_\_\_\_

20 50%

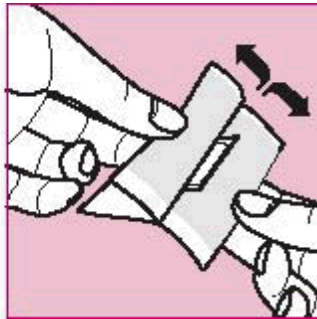
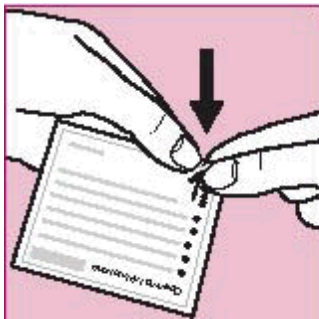
2

\_\_\_\_\_/\_\_\_\_\_

3 72

1

2



3

4

-

5

\_\_\_\_\_

FEN-EMA-1

216

40

6

25 g/

25 g/

100 g/

5%

5%

1%

3

1%

3

1%

	% (N=216)	% (N=200)
	4.6	0
	10.2	6.5
	1.4	0



3

1%

	% (N=216)	% (N=200)	
	19.0	2.5	
	10.2	4.0	
	2.3	0.5	
	3.7	1.0	
	40.7	16.5	
	25.9	2.5	
	8.8	1.0	
	2.8	1.5	
	2.3	0	
	6.5	1.0	
	3.2	2.0	
	1.9	1.0	
	4.2	1.5	
	6.5	3.0	
	6.5	2.0	
	3.7	0.5	
	2.3	0	
	1.4	1.0	
25 g/	50 g/	75 g/	100 g/

3

11

FEN-EMA-

1

N=1854 ≥1%

4



3

2-18

N=289

≥1%

6

6

3

≥1%

	<b>% (N=289)</b>
	3.1
	3.8
	5.5
	3.8
	2.1
	1.7
	16.3
	5.2
	2.1
	2.1
	1.0
	1.0
	33.9
	23.5
	13.5
	12.8
	8.7
	3.8
	2.1
	12.8
	5.9
	3.5
	3.1
	1.7
	3.1
	4.5
	2.1
	1.4
	1.4

\_\_\_\_\_



40

20-27

50%

24

/

20~27

2

24

2

24~72

24

24~72

CNS

[CSA]

CSA

CNS

CNS



CNS

CNS

CNS

CNS

CNS

CNS

CNS

CYP3A4

CYP3A4

CYP3A4

CYP3A4

CYP3A4

CYP3A4

CYP3A4

CYP3A4

CYP3A4

CYP3A4

1

spa

40°C

1/3

**1**

**AUC**

**C<sub>max</sub>**

**120% 61%**

10%

/

/

/

/

5-

5-

5-

5-

SSRI

5-

SNRI

TCA

5-HT3

5-

5-

[

(MAOI)

]

5-

5-

/

5-

OIH

OIH

OIH

/

---

\_\_\_\_\_

2

/

P450 3A4 CYP3A4

CYP3A4

CYP3A4

CYP3A4

CYP3A4

CYP3A4

CYP3A4

MAOI

5-

14

5-

5-

5-

SSRI

5-

SNRI

MAOI

5-

/

/

50%

20-27

72-96

---

---

---

/

/

50 µg /kg

\_\_\_\_\_

- -

\_\_\_\_\_

Ames

DNA

BALB/c 3T3

CHO

0.025 0.1

0.4mg/kg/

mg/m<sup>2</sup>

100µg/

1.6

28

14

16

12

0.3

2

10 100 500µg/kg/

mg/m<sup>2</sup>

100 µg /

2

6 18

0.01 0.03mg/kg

0.03mg/kg

mg/m<sup>2</sup>

100 µg

/ 0.1

6 18

0.025 0.1 0.4mg/kg



100µg/ 3 0.4mg/kg mg/m<sup>2</sup>  
 -  
 Wistar 6 3  
 0.025 0.1 0.4mg/kg 4  
 mg/m<sup>2</sup> 100µg/  
 0.4 1.6  
 28 50  
 2 33 100 µg/kg/  
 AUC<sub>0-24h</sub> 100µg/ 0.16 0.39  
 ———  
 72  
 12~24 72  
 72  
 AUC C<sub>max</sub> 40%  
 24 72  
 14% 0~26%  
 10 AUC  
 2.2 61%  
 ———  
 3-10 L/kg  
 95% 77-100%  
 ———

CYP3A4  
(Norfentanyl) 92%

24 50% 72 17 13~22  
20~27 7 3~12

72 75% 10% 9%

$t_{1/2}$  34

g/h 2 250 2-17 12-300  
2-5 6-10 L/h/kg

11-16 80% 25% 11-16 2

50 g/h

$t_{max}$   $(t_{1/2})$   $C_{max}$  AUC  
35% 73%

AUC B Child-Pugh =8 C Child-Pugh =12.5  
A Child-Pugh =5.5 1.36 3.72

15 25

5 /

24

JM20150004	25 g/	4.2mg/	50 g/	8.4mg/
JM20190002	12 g/	2.1mg/	75 g/	12.6mg/

12 g/	2.1mg/	H20150591
25 g/	4.2mg/	H20150592
50 g/	8.4mg/	H20150594
75 g/	12.6mg/	H20150593

12 g/	2.1mg/	TNI20160301
25 g/	4.2mg/	TNI20160302
50 g/	8.4mg/	TNI20160501
75 g/	12.6mg/	TNI20160303

25 g/	4.2mg/	J20160062
50 g/	8.4mg/	J20160061

Janssen-Cilag NV

Antwerpseweg 15-17, B, B