

2017 11 07
2019 02 21
2019 05 22
2019 05 24
2020 03 11
2020 12 11
2021 08 05

产

可

®

Ustekinumab Injection

Wusinu Dankang Zhusheye

L-

L-

80

MTX

PUVA

A

TNF

45mg/0.5ml/

90mg/1.0ml/

产

45 mg

4

12

100 kg

100 kg

90 mg

4

12

45 mg

90 mg

28

IV

1

8 90mg

12

90mg

1

		^a	130 mg
55 kg		260 mg	2
55 kg	85 kg	390 mg	3
85 kg		520 mg	4

a 6 mg/kg

8

12

1

8

1

8

12

1

16

8

1

16

/

8

1

45mg/0.5ml/

90mg/1.0ml/

"

"

"

"

" "

5%

III	5,884	4,135	/	12	II	1,749
6	4,105	1	2,846			
			4	1,482	5	838
2						
	1/10	1/100	1/10	1/1,000	1/100	
	1/10,000	1/1,000		1/10,000		

2

1.38				1.35			
		0.03		829		27	
	0.03		385		11		
							5,884
		10,953			0.99		
	3.2			1.0			
0.6				0.91			
0.02		10,953		178			
<hr/>							
					0.12	100	
	829		1		0.26	100	385
		1					0.48
100		829		4		0.52	100
	385		2				
5,884			10,935			1.0	
	3.2				1.0		
0.6		10,935					58
					0.53	100	
		=0.87 [95%		0.66	1.14]		
							0.49
100		10,919		53			
	4:1						
<hr/>							

1%

466

2.4%

470

2.6%

1

1

RPLS

12

RPLS

RPLS

RPLS

RPLS

12.4%

3%

/

CT

-

T

T cell enzyme-linked immune-spot assay T-SPOT.TB T

Quanti FERON-TB Gold QFT-G

IL-12/IL-23

BCG

IL-12/IL-23

60

PUVA

[BCG]

15

2

MTX

1-3

15

/

15

18

65

65

65

III

100

5%

90%

MTX

NSAID

6-

TNF

IL-12

IL-23

CYP450

10 ng/ml

IL-12

/

IL-23

CYP450

CYP1A2

2B6

2C9

2C19

2D6

3A4

CYP450

IL-1

IL-6

IL-10

TNF

IFN

IL-12

IL-23

CYP450

CYP450

CYP450

MTX

6 mg/kg

1 2 PASI
 17-18 BSA 20
 DLQI 10-12 1/3 1 1/4 2
 PsA 3
 12 PASI 75
 3 4
 3 1 PHOENIX 1 2 PHOENIX 2

		12	28			
		2	0	4	3	
					4	
					0	
					16	
			45 mg	90 mg	45 mg	90 mg
		255	255	256	250	243
PASI 50	%	26 (10%)	213 (84%) ^a	220 (86%) ^a	228 (91%)	234 (96%)
PASI 75	%	8 (3%)	171 (67%) ^a	170 (66%) ^a	178 (71%)	191 (79%)
PASI 90	%	5 (2%)	106 (42%) ^a	94 (37%) ^a	123 (49%)	135 (56%)
PGA ^b	%	10 (4%)	151 (59%) ^a	156 (61%) ^a	146 (58%)	160 (66%)
100 kg		166	168	164	164	153
PASI 75	%	6 (4%)	124 (74%)	107 (65%)	130 (79%)	124 (81%)
100 kg		89	87	92	86	90
PASI 75	%	2 (2%)	47 (54%)	63 (68%)	48 (56%)	67 (74%)
		410	409	411	397	400
PASI 50	%	41 (10%)	342 (84%) ^a	367 (89%) ^a	369 (93%)	380 (95%)

PASI 75	%	15 (4%)	273 (67%) ^a	311 (76%) ^a	276 (70%)	314 (79%)
PASI 90	%	3 (1%)	173 (42%) ^a	209 (51%) ^a	178 (45%)	217 (54%)
PGA ^b		18 (4%)	277 (68%) ^a	300 (73%) ^a	241 (61%)	279 (70%)
	%					
100 kg		290	297	289	287	280
PASI 75	%	12 (4%)	218 (73%)	225 (78%)	217 (76%)	226 (81%)
100 kg		120	112	121	110	119
PASI 75	%	3 (3%)	55 (49%)	86 (71%)	59 (54%)	88 (74%)

^a 45 mg 90 mg p 0.001

^b PGA=

4 3 ACCEPT 12

		24 2 50mg	2 0 4
			45 mg 90 mg
		347	209 347
PASI 50	%	286 (82%)	181 (87%) 320 (92%) ^a
PASI 75	%	197 (57%)	141 (67%) ^b 256 (74%) ^a
PASI 90	%	80 (23%)	76 (36%) ^a 155 (45%) ^a
PGA		170 (49%)	136 (65%) ^a 245 (71%) ^a
	%		
100 kg		251	151 244
PASI 75	%	154 (61%)	109 (72%) 189 (77%)

100 kg		96	58	103
PASI 75	%	43 (45%)	32 (55%)	67 (65%)

^a 45 mg 90 mg p 0.001

^b 45 mg p=0.012

1 PASI 75
 p 0.001 1 52
 PASI 75 89%
 63% p 0.001 18
 76 PASI 75 84%
 19% 3 148
 PASI 75 82% 5 244
 PASI 75 80%
 PASI 50%
 85% 12 PASI 75
 1 2 12 DLQI
 28
 2 4 12 24
 1
 SF-36 VAS
 2
 HADS WLO
 CDAI 220 450
 8
 UNITI-1 UNITI-2 44 IM-
 UNITI 52

1409 UNITI-1 n=769 UNITI-2 n=640
6 CDAI 100
8
75%
0
6 mg/kg 1 130 mg
UNITI-1 TNF 48%
1 TNF 52% 2 3 TNF
29.1% 36.4% TNF 69.4%
UNITI-2
TNF 68.6% TNF
31.4%
UNITI-1 UNITI-2
5 3
8
130 mg

5 UNITI-1 UNITI-2

		*	**	
8	18 (7.3%)	52 (20.9%) ^a	41 (19.6%)	84 (40.2%) ^a
100	53 (21.5%)	84 (33.7%) ^b	60 (28.7%)	116 (55.5%) ^a
6				

8	100	50 (20.2%)	94 (37.8%) ^a	67 (32.1%)	121 (57.9%) ^a
70	3	67 (27.1%)	101 (40.6%) ^b	66 (31.6%)	106 (50.7%) ^a
70	6	75 (30.4%)	109 (43.8%) ^b	81 (38.8%)	135 (64.6%) ^a

CDAI

150

CDAI

100

70

CDAI

70

* TNF

**

^a p 0.001

^b p 0.01

IM-UNITI

UNITI-1

UNITI-2

8

100

388

90 mg

8

90 mg

12

44

44

6

6 IM-UNITI

44

52

	36%	53% ^a	49% ^b
	44%	59% ^b	58% ^b
	30%	47% ^a	43% ^c

		46% (36/79)	67% (52/78) ^a	56% (44/78)
	CRD3002 †	44% (31/70)	63% (45/72) ^c	57% (41/72)
	TNF	49% (25/51)	65% (34/52) ^c	57% (30/53)
	CRD3001 §	26% (16/61)	41% (23/56)	39% (22/57)

CDAI 150 CDAI
 100
 *
 † 100
 ‡ TNF
 § TNF /
^a p 0.01
^b p 0.05
^c p 0.05
 IM-UNITI 29/129 12 1
 8 1
 CDAI 220 CDAI 100
 41.4% 16
 UNITI-1 UNITI-2 8
 476 IM-UNITI
 90 mg 8 50.5%
 8 44
 68.1% 50.2%
 131 51 90 mg
 8 1
 24 51 70.6%
 16 39.2%

IM-UNITI 44
 TNF 92

252
 SES-CD /
 /
 8 n=155 = -2.8
 SES-CD n=97 = -0.7 p=0.012

8.8% n=26 12/15 80%
 44
 50% 45.5% 5/11

36 UNITI-1 IBDQ SF-36 8
 UNITI-2 IBDQ SF-
 UNITI-2 SF-36 44 IM-UNITI

p40 IgG1 IL-12 IL-23
 IL-12 IL-23
 CD⁴⁺T
 IL-12R 1
 IL-12 IL-23

IL-12 IL-23 p40

					2
		45mg/kg	mg/kg		
45					
					2
IL-12/IL-23p40			50mg/kg		
	-				2
1					100
	90mg	4	100		
	-				
	33		2		
	100		22.5mg/kg	1	45mg/kg
1			6		
					IL-
12		IL-12/IL-23 p40			IL-12/IL-23 p40
	IL-12	IL-23	IL-12		

26
45mg/kg 1

10

26

仅

—

8.5

90 mg

45 mg

90 mg

T_{max}

T_{max}

57.2%

—

ml/kg

V_z

57~83

—

—

CL

1.99~2.34 ml/ /kg

$t_{1/2}$

3

15~32

CL/F

V/F

0.465 L/

15.7 L

$t_{1/2}$

3

CL/F

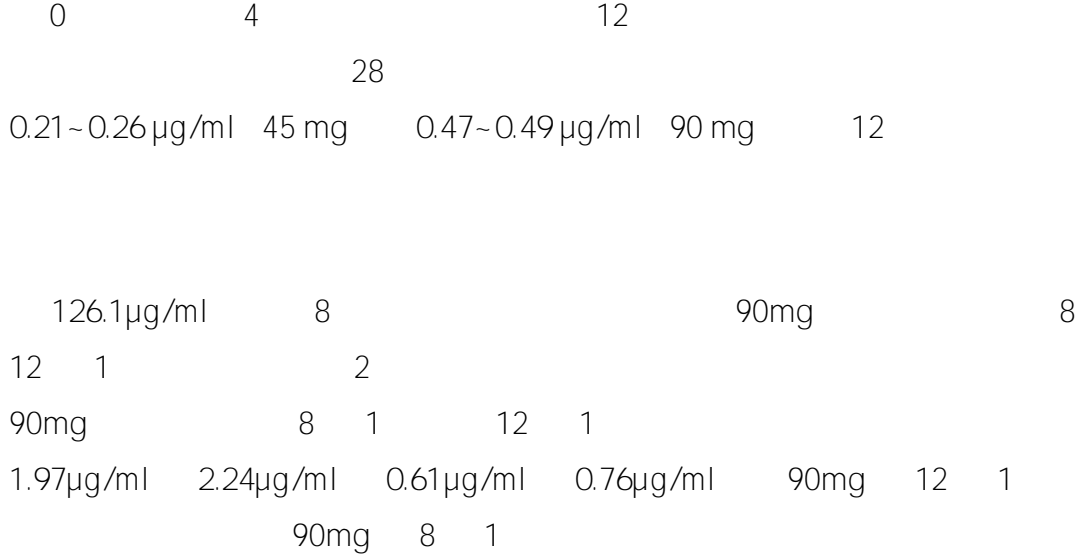
—

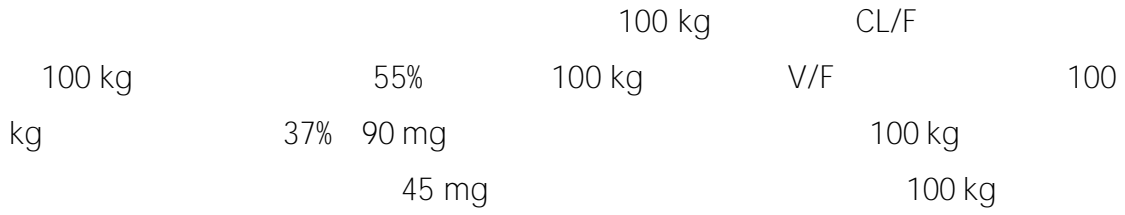
0.09 mg/kg~4.5 mg/kg

24 mg~240 mg

C_{max}

AUC





CL/F V/F

65

12-17

CYP450

					IL-12	IL-23	CYP450
			10 ng/ml	IL-12	/	IL-23	CYP450
CYP1A2	2B6	2C9	2C19	2D6	3A4		

2~8

1ml I
1
1 /
36

JS20210031

45mg/0.5ml/ S20170047

90mg/1.0ml/ S20170046

Janssen-Cilag International NV
Turnhoutseweg 30, B-2340 Beerse, Belgium

代

Cilag AG

Hochstrasse 201, 8200 Schaffhausen, Switzerland

19

710304

400 888 9988

(029)82576616

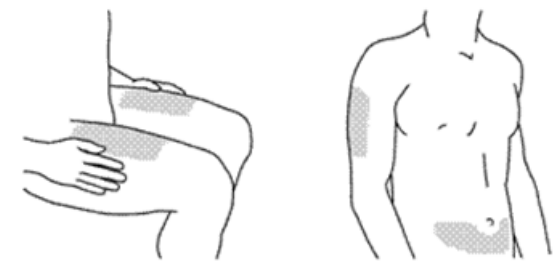
<http://www.xian-janssen.com.cn>

- 45 mg 45 mg
- 90 mg 45 mg

- 90 mg 90 mg

2

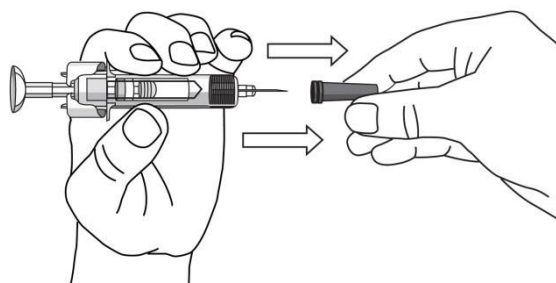
5 cm



*灰色区域为推荐的注射部位。

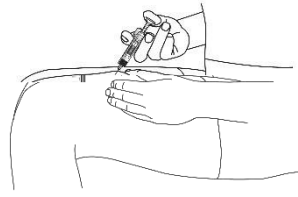
2

外



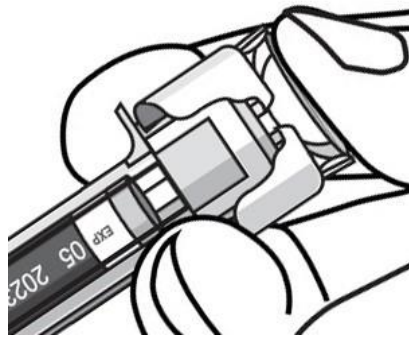
3

4



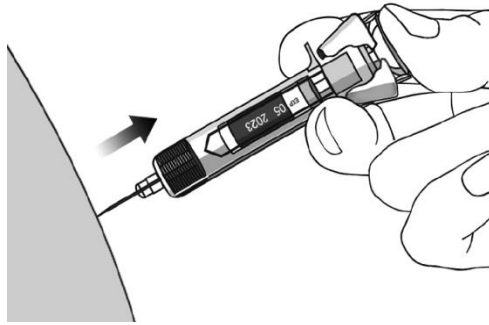
4

5



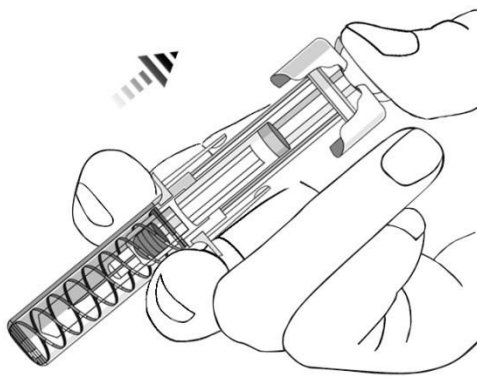
5

6



6

7



7

