

2019 12 26  
2020 02 21  
2020 06 22  
2020 07 02

®

Guselkumab Injection  
Gusaiqiyou Dankang Zhusheye

L- L- 80

100 mg/1 mL/

— 0 4 100 mg 8

16

/



48 III 0.7% 0.3%  
156 0.5%

52 7% 0.4% II III 6%  
156 9% III

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TB  
TB

TB

\_\_\_\_\_

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12

2

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30

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12

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IgG

30

MRHD  
MRHD 6 30

—

IgG

—

18

2636

65

160

65

13

75

65

—

CYP450

CYP450

IL-1 IL-6 IL-10

TNF

CYP3A4 CYP2C9 CYP2C19 CYP1A2  
CYP2D6

CYP450

CYP450

987 mg 10 mg/kg  
300 mg

3

III

VOYAGE 1 VOYAGE 2  
VOYAGE 1 VOYAGE 2 1829  
N=825  
0 4 100 mg 8 q8w 48 VOYAGE 1  
20 VOYAGE 2 N=582 0 80  
mg 1 40 mg 40 mg q2w 48  
VOYAGE 1 23 VOYAGE 2  
N=422 16 20 8 100 mg  
VOYAGE 1 0 52  
8 28 VOYAGE 2 0  
8 8 PASI 90  
28 PASI 50%  
4 8 0  
PASI 90 28 32 8  
VOYAGE 2 76  
8  
VOYAGE 1 2 BSA  
22% 24% PASI 19 DLQI  
14 14.5 25% 23% IGA  
19% 18%  
VOYAGE 1 2 32% 29%  
54% 57% 62% 64%  
21% 11% α  
TNFα 10% IL-12/IL-23

VOYAGE 1 2 16 IGA  
 IGA 0/1 PASI 90 2

16

24

48

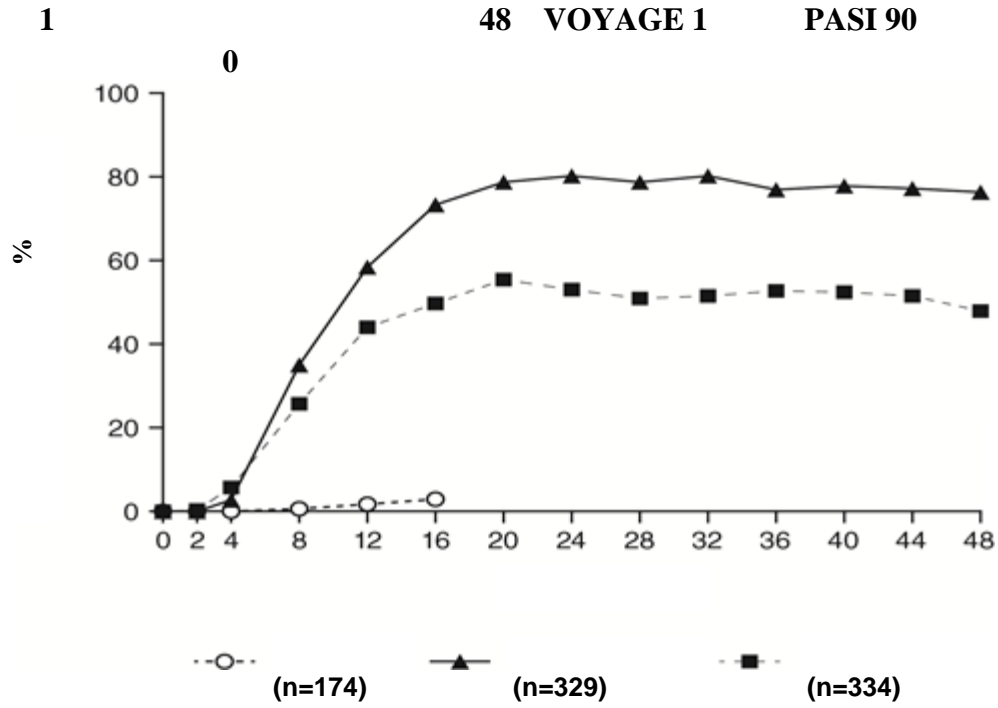
2

**2 VOYAGE 1 VOYAGE 2**

	%					
	VOYAGE 1			VOYAGE 2		
	N=174	N=329	N=334	N=248	N=496	N=248
<b>16</b>						
PASI 75	10 (5.7)	300 (91.2) <sup>a</sup>	244 (73.1) <sup>b</sup>	20 (8.1)	428 (86.3) <sup>a</sup>	170 (68.5) <sup>b</sup>
PASI 90	5 (2.9)	241 (73.3) <sup>c</sup>	166 (49.7) <sup>b</sup>	6 (2.4)	347 (70.0) <sup>c</sup>	116 (46.8) <sup>b</sup>
PASI 100	1 (0.6)	123 (37.4) <sup>a</sup>	57 (17.1) <sup>d</sup>	2 (0.8)	169 (34.1) <sup>a</sup>	51 (20.6) <sup>d</sup>
IGA 0/1	12 (6.9)	280 (85.1) <sup>c</sup>	220 (65.9) <sup>b</sup>	21 (8.5)	417 (84.1) <sup>c</sup>	168 (67.7) <sup>b</sup>
IGA 0	2 (1.1)	157 (47.7) <sup>a</sup>	88 (26.3) <sup>d</sup>	2 (0.8)	215 (43.3) <sup>a</sup>	71 (28.6) <sup>d</sup>
<b>24</b>						
PASI 75	-	300 (91.2)	241 (72.2) <sup>e</sup>	-	442 (89.1)	176 (71.0) <sup>e</sup>
PASI 90	-	264 (80.2)	177 (53.0) <sup>b</sup>	-	373 (75.2)	136 (54.8) <sup>b</sup>
PASI 100	-	146 (44.4)	83 (24.9) <sup>e</sup>	-	219 (44.2)	66 (26.6) <sup>e</sup>
IGA 0/1	-	277 (84.2)	206 (61.7) <sup>b</sup>	-	414 (83.5)	161 (64.9) <sup>b</sup>
IGA 0	-	173 (52.6)	98 (29.3) <sup>b</sup>	-	257 (51.8)	78 (31.5) <sup>b</sup>
<b>48</b>						
PASI 75	-	289 (87.8)	209 (62.6) <sup>e</sup>	-	-	-
PASI 90	-	251 (76.3)	160 (47.9) <sup>b</sup>	-	-	-
PASI 100	-	156 (47.4)	78 (23.4) <sup>e</sup>	-	-	-
IGA 0/1	-	265 (80.5)	185 (55.4) <sup>b</sup>	-	-	-
IGA 0	-	166 (50.5)	86 (25.7) <sup>b</sup>	-	-	-

<sup>a</sup> p 0.001  
<sup>b</sup> p 0.001  
<sup>c</sup> p 0.001  
<sup>d</sup>  
<sup>e</sup> p 0.001

0.001 8 2 PASI PASI 90 p  
 20 VOYAGE 1 2 48  
 VOYAGE 1 1



VOYAGE 1

PASI 90

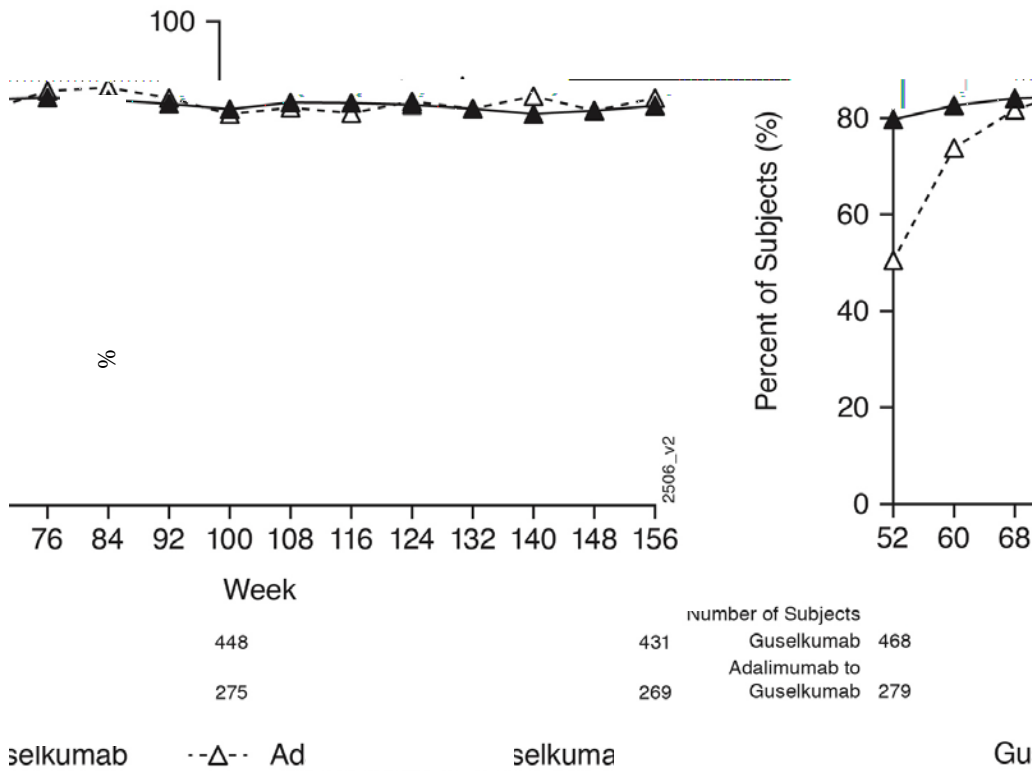
52    0    52    156

52    76    PASI 90    156

2

2 VOYAGE 1 PASI 90





PASI

Group	VOYAGE 1	VOYAGE 2	VOYAGE 3	VOYAGE 4	VOYAGE 5	VOYAGE 6	VOYAGE 7	VOYAGE 8	VOYAGE 9	VOYAGE 10	VOYAGE 11	VOYAGE 12
[ss-IGA]	2	16										
[hf-PGA]												
[f-PGA]												

Group	VOYAGE 1	VOYAGE 2	VOYAGE 3	VOYAGE 4	VOYAGE 5	VOYAGE 6	VOYAGE 7	VOYAGE 8	VOYAGE 9	VOYAGE 10	VOYAGE 11	VOYAGE 12
[ss-IGA]	2	16										
[hf-PGA]												
[f-PGA]												

Group	VOYAGE 1	VOYAGE 2	VOYAGE 3	VOYAGE 4	VOYAGE 5	VOYAGE 6	VOYAGE 7	VOYAGE 8	VOYAGE 9	VOYAGE 10	VOYAGE 11	VOYAGE 12
[ss-IGA]	2	16										
[hf-PGA]												
[f-PGA]												

2 48 VOYAGE 1 [NAPSI] p 0.001 3 24 VOYAGE 1  
 p 0.05 24 [VOYAGE 2] 48 [VOYAGE 1]

**3 VOYAGE 1 VOYAGE 2**

	VOYAGE 1			VOYAGE 2		
<b>ss-IGA (N)<sup>a</sup></b>	145	277	286	202	408	194
ss-IGA 0/1 <sup>b</sup> , n (%)						
16	21 (14.5)	231 (83.4) <sup>c</sup>	201 (70.3) <sup>d</sup>	22 (10.9)	329 (80.6) <sup>c</sup>	130 (67.0) <sup>d</sup>
<b>hf-PGA (N)<sup>a</sup></b>	43	90	95	63	114	56
hf-PGA 0/1 <sup>b</sup> , n (%)						
16	6 (14.0)	66 (73.3) <sup>e</sup>	53 (55.8) <sup>d</sup>	9 (14.3)	88 (77.2) <sup>e</sup>	40 (71.4) <sup>d</sup>
<b>f-PGA (N)<sup>a</sup></b>	88	174	173	123	246	124
f-PGA 0/1, n (%)						
16	14 (15.9)	68 (39.1) <sup>e</sup>	88 (50.9) <sup>d</sup>	18 (14.6)	128 (52.0) <sup>e</sup>	74 (59.7) <sup>d</sup>
<b>NAPSI (N)<sup>a</sup></b>	99	194	191	140	280	140
SD						
16	-0.9 (57.9)	34.4 (42.4) <sup>e</sup>	38.0 (53.9) <sup>d</sup>	1.8 (53.8)	39.6 (45.6) <sup>e</sup>	46.9 (48.1) <sup>d</sup>

<sup>a</sup> ss-IGA f-PGA hf-PGA 2 NAPSI 0  
<sup>b</sup> ss-IGA / hf-PGA 2  
<sup>c</sup> p 0.001  
<sup>d</sup>  
<sup>e</sup> p 0.001

/

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VOYAGE 1 2 16 [DLQI]

4 24 VOYAGE 1 2 48 VOYAGE 1  
 VOYAGE 1 156 5

**4 16 VOYAGE 1 VOYAGE 2**

	VOYAGE 1			VOYAGE 2		
<b>DLQI</b>	170	322	328	248	495	247
16	-0.6 (6.4)	-11.2 (7.2) <sup>c</sup>	-9.3 (7.8) <sup>b</sup>	-2.6 (6.9)	-11.3 (6.8) <sup>c</sup>	-9.7 (6.8) <sup>b</sup>

<b>PSSD</b>	0	129	248	273	198	410	200
	=0 n %						
16		1 (0.8)	67 (27.0) <sup>a</sup>	45 (16.5) <sup>b</sup>	0	112 (27.3) <sup>a</sup>	30 (15.0) <sup>b</sup>
<b>PSSD</b>	0	129	248	274	198	411	201
	=0 n %						
16		0	50 (20.2) <sup>a</sup>	32 (11.7) <sup>b</sup>	0	86 (20.9) <sup>a</sup>	21 (10.4) <sup>b</sup>

<sup>a</sup> p 0.001

<sup>b</sup>

<sup>c</sup>

p 0.001

### 5 VOYAGE 1

		76	<sup>a</sup> 156	<sup>b</sup> 76	156
<b>DLQI</b>	>1 n	445	411	264	251
DLQI 0/1		337 (75.7%)	307 (74.7%)	198 (75.0%)	190 (75.7%)
<b>PSSD</b>	>0	347	319	227	214
	=0 n %	136 (39.2%)	129 (40.4%)	99 (43.6%)	96 (44.9%)
<b>PSSD</b>	>0	347	319	228	215
	=0 n %	102 (29.4%)	93 (29.2%)	71 (31.1%)	69 (32.1%)

VOYAGE 2 16

36

[SF-36]

[HADS]

[WLQ]

28

SF 36

HADS

WLQ

48

156

NAVIGATE

NAVIGATE 16

IGA 2

N=871

0

4

45 mg

100 kg

90 mg

100 kg

16

268

IGA

2

N=133

12

16

20

N=135

8

VOYAGE 1 2

12

24

IGA

0/1

2

12-24

IGA

0/1

2

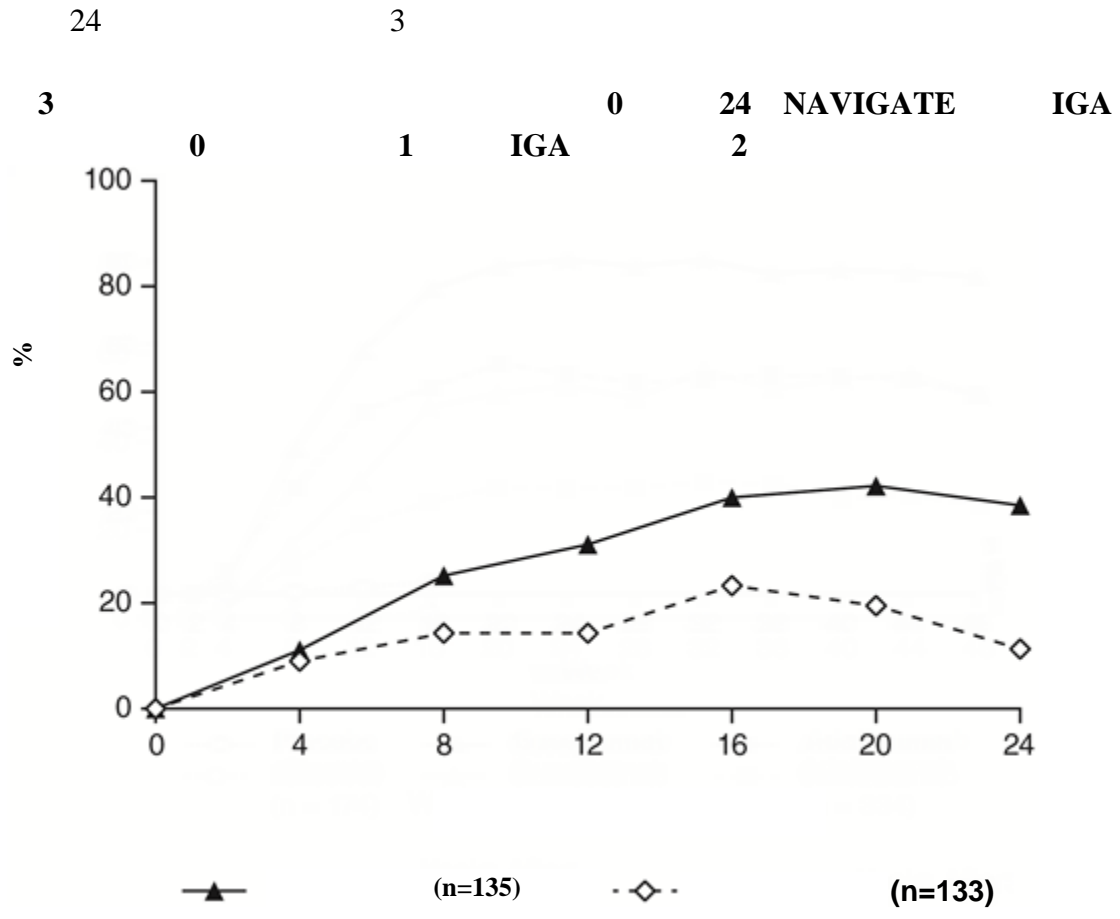
IGA

0/1

2

2

1.5 vs 0.7 p 0.001  
 IGA 0/1 2 31.1% 14.3% p=0.001 PASI 90 48%  
 23% p 0.001 4 11.1% 9.0%



**ECLIPSE**

N=514 0 1 2 3 4 N=534 0 4 100 mg 8  
 44 300 mg 4

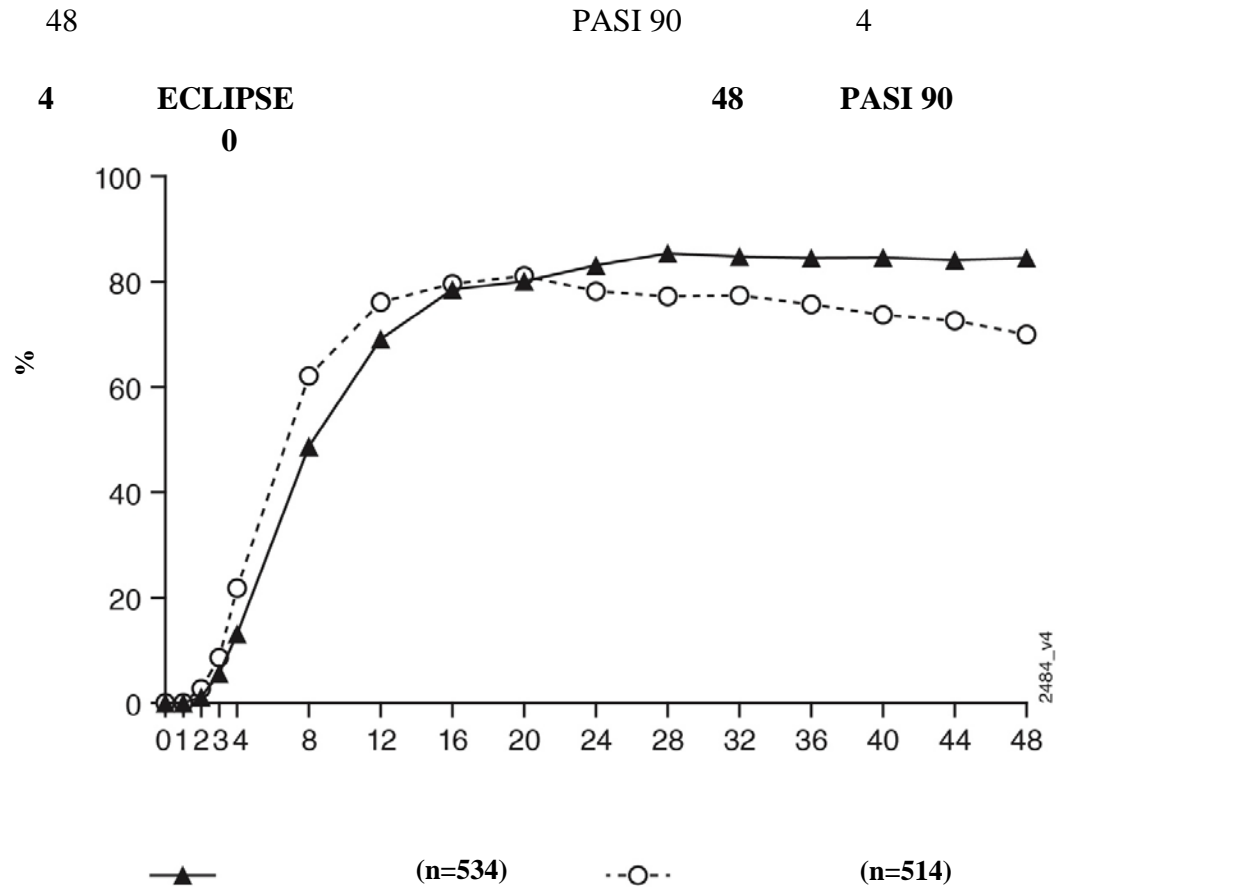
18 24% IGA BSA 20% PASI

48 PASI 90  
 84.5% vs. 70.0% p<0.001 PASI 6

6 ECLIPSE PASI	%	
	N=534	N=514

48	PASI 90	451 (84.5%) <sup>a</sup>	360 (70.0%)
12	48 PASI 75	452 (84.6%) <sup>b</sup>	412 (80.2%)
12	PASI 75	477 (89.3%) <sup>c</sup>	471 (91.6%)
12	PASI 90	369 (69.1%) <sup>c</sup>	391 (76.1%)
48	PASI 100	311 (58.2%) <sup>c</sup>	249 (48.4%)

<sup>a</sup> p<0.001  
<sup>b</sup> p < 0.001      p=0.062  
<sup>c</sup>



IL-23      IgG1λ      23 IL-23      p19  
IL-23

IL-17A IL-17F IL-22

mg/kg 2  
100 mg/kg MRHD 15 25 mg/kg  
mg/kg 2  
MRHD 60

MRHD 6 30 3 1 10 mg/kg 50mg/kg mg/kg  
6  
28

SD 100 mg 5.5 ±  
C<sub>max</sub> 8.09 ± 3.68 mcg/mL ±

0 4 8 100 mg 20  
III ± SD  
1.15 ± 0.73 mcg/mL 1.23 ± 0.84 mcg/mL

100 mg  
49%

10 L V<sub>z</sub> 7-

IgG IgG mAb

0.479 L/

15-18

CL  
T<sub>1/2</sub>

0.288 -  
17

/

10 mg - 300 mg

C<sub>max</sub> AUC

1384

65

70

65

65

4

75

CL/F

/

IgG mAb

IgG mAb

2 8°C

100 mg

1 mL

1 /

24

JS20190043

S20190044

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

: Cilag AG  
: Hochstrasse 201, 8200 Schaffhausen,

:  
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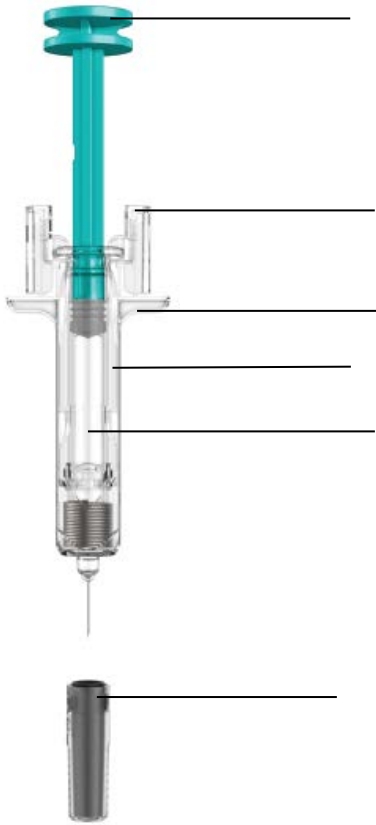
19

: 710304  
: 400 888 9988  
: (029) 8257 6616  
: <http://www.xian-janssen.com.cn>

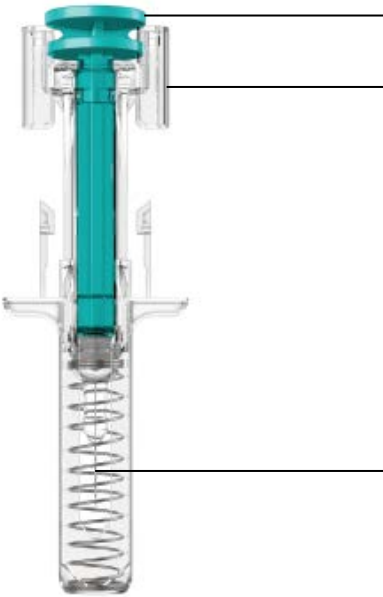




2°C-8°C

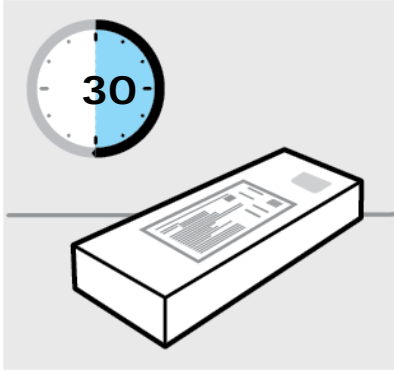


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  - 1
  - 1
  - 1
- 3

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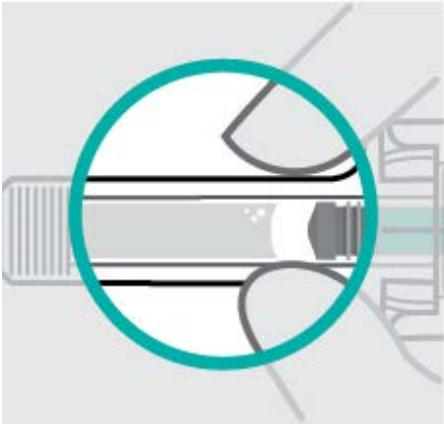
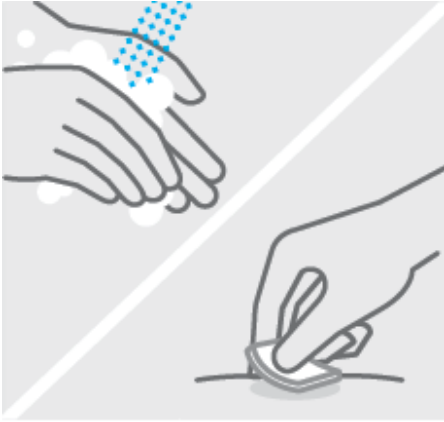
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**“EXP”**

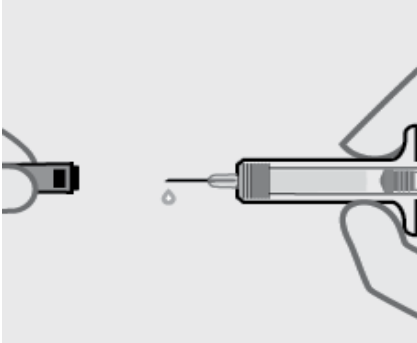


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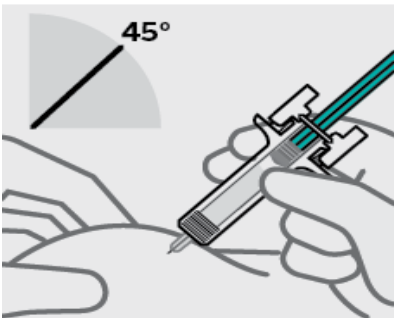
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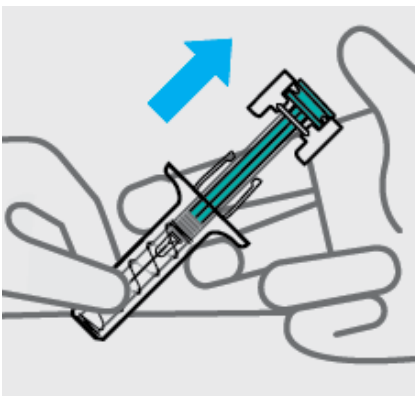
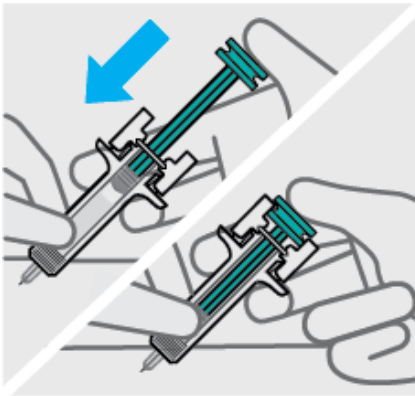
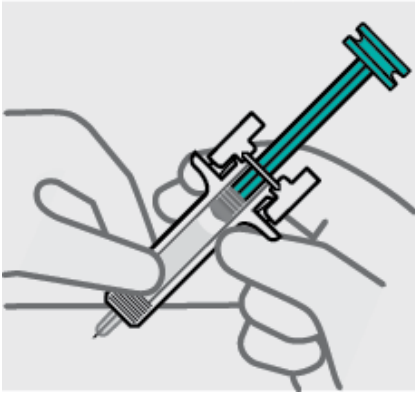
2.



5



45



3.

