

2020 08 26

®

Guselkumab Injection

Gusaiqiyou Dankang Zhusheye

L-

L-

80

100 mg/1 mL/

—

0

4

100 mg

8

16

/

—

“

”

ADR

1
MedDRA
1/100 1/10 1/1,000 1/100 1/10
1/1,000 1/10,000 1/10,000

1

		ADR

III

4.9%

0.7%

156

1.1%

156

48

III

156 0.7%
0.5%

0.3%

III
6%

52

II

7%

0.4%

III

156

9%

•
•
•

TB

TB

TB

2

12

30

“ ”

.

12

IgG

30

MRHD

MRHD

6

30

IgG

18

2711 65 165 65
 15 75 65

CYP450

IL-10 TNF CYP450 IL-1 IL-6

CYP3A4 CYP2C9 CYP2C19 CYP1A2
 CYP2D6

CYP450 CYP450

987 mg 10 mg/kg
 300 mg

4 III (VOYAGE 1, VOYAGE 2,
 NAVIGATE ORION)

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 VOYAGE 2 0
 28 PASI
 90 8
 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 VOYAGE 1 VOYAGE 2

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

a
b
c
d
e

p 0.001

p 0.001

p 0.001

p 0.001

p 0.001

8

20

48

VOYAGE 1

2

PASI

PASI 90

VOYAGE 1

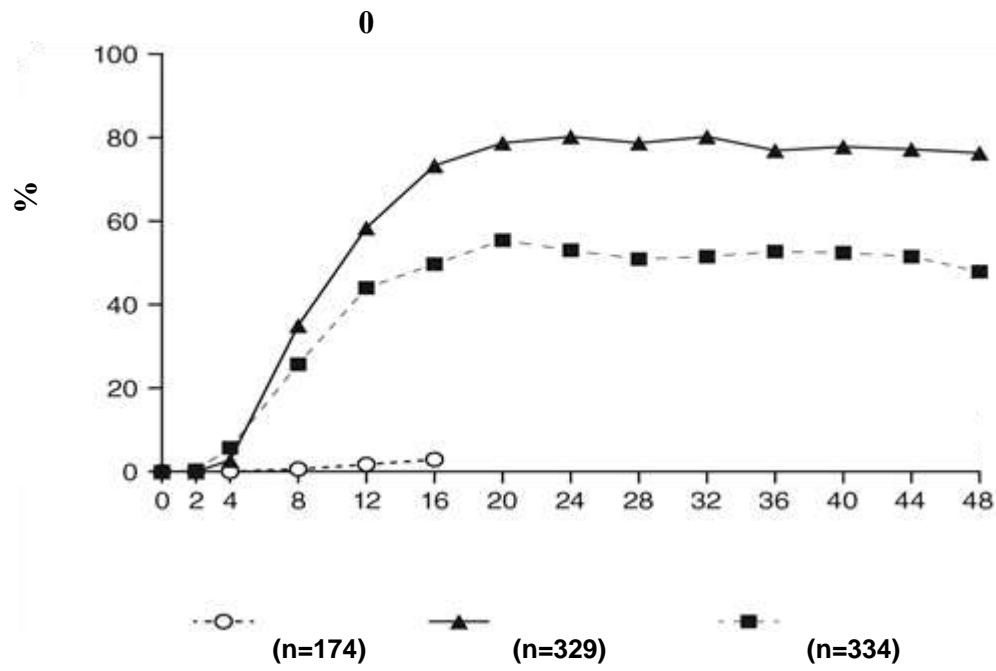
2

1

1

48 VOYAGE 1

PASI 90

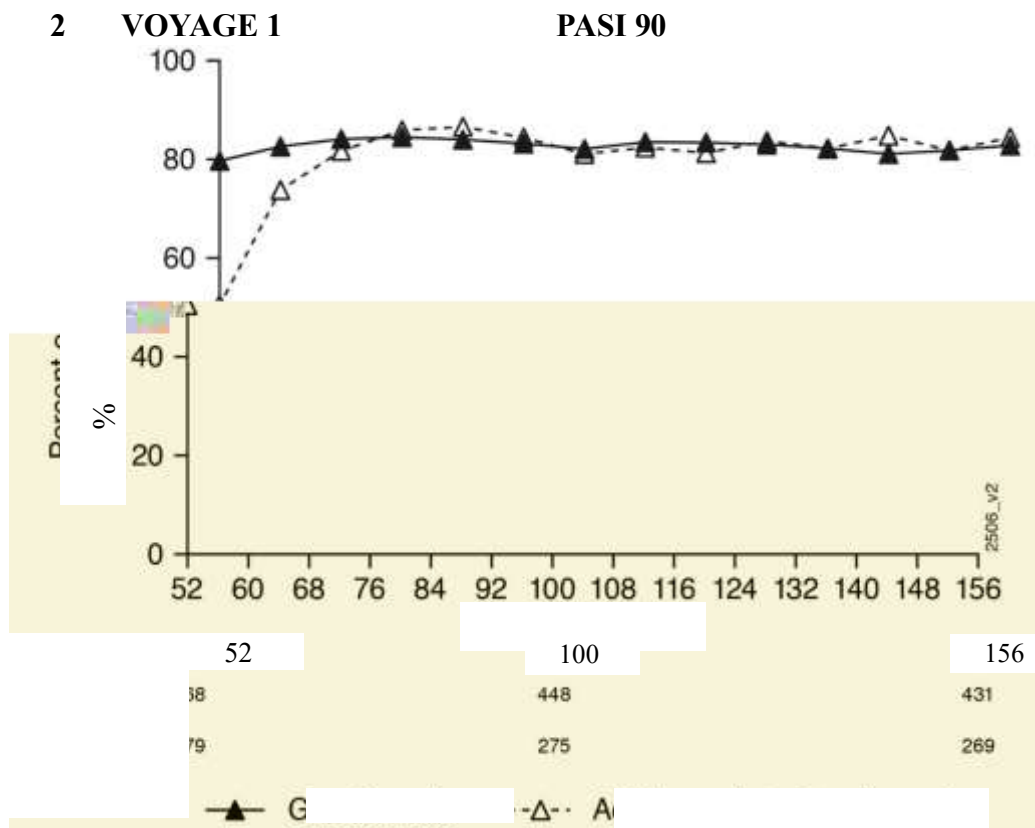


VOYAGE 1 52

156 PASI 90 0 52

52 76 PASI 90

156 2



PASI

	VOYAGE 2	48				88.6%
	PASI 90	28		36.8%	PASI 90	
p	0.001		4	PASI 90	PASI	
90		15				
		20	80%		PASI 90	
	VOYAGE 2			28		PASI 90
	112		66%	76%		
20	44	PASI 90				28
	PASI 90	95		36%	41%	
	20	44		PASI 90		

	VOYAGE 1	2	16			
		[ss-IGA]		/	[hf-PGA]	
		[f-PGA]			[NAPSI]	p 0.001
3	24	VOYAGE 1	2	48	VOYAGE 1	
						p 0.001
						24
[VOYAGE 2]	48	[VOYAGE 1]				p 0.05

3 VOYAGE 1 VOYAGE 2

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

^a ss-IGA f-PGA hf-PGA 2 NAPSI 0

^b ss-IGA / hf-PGA 2

^c p 0.001

^d

^e p 0.001

VOYAGE 1 2

16

[DLQI]

1 2

48

VOYAGE 1

VOYAGE 1

156

5

24 VOYAGE

4 16 VOYAGE 1 VOYAGE 2

	VOYAGE 1			VOYAGE 2		
DLQI	170	322	328	248	495	247
16	-0.6 (6.4)	-11.2 (7.2) ^c	-9.3 (7.8) ^b	-2.6 (6.9)	-11.3 (6.8) ^c	-9.7 (6.8) ^b
PSSD 0 =0 n %	129	248	273	198	410	200
16	1 (0.8)	67 (27.0) ^a	45 (16.5) ^b	0	112 (27.3) ^a	30 (15.0) ^b
PSSD 0 =0 n %	129	248	274	198	411	201
16	0	50 (20.2) ^a	32 (11.7) ^b	0	86 (20.9) ^a	21 (10.4) ^b

^a p 0.001

^b

^c

p 0.001

5 VOYAGE 1

	^a	^b
	76	156
DLQI >1 n	445	411
DLQI 0/1	337 (75.7%)	307 (74.7%)
PSSD >0	347	319
=0 n %	136 (39.2%)	129 (40.4%)
PSSD >0	347	319
=0 n %	102 (29.4%)	93 (29.2%)

VOYAGE 2 16

36

[SF-36]

[HADS]

[WLQ]

28

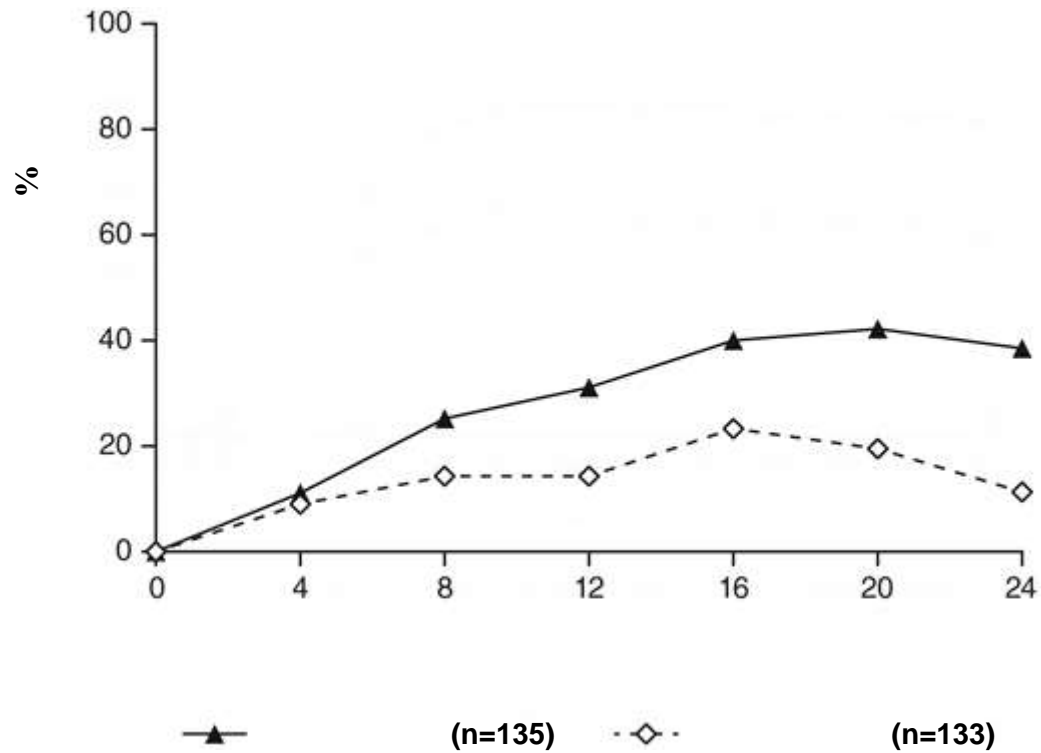
SF 36 HADS WLQ

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
 0/1 2 12 24 IGA
 IGA IGA 0/1 2 12-24
 IGA 0/1 2 2 1.5
 vs 0.7 p 0.001 12 IGA 0/1
 2 31.1% 14.3% p=0.001 PASI 90 48%
 23% p 0.001 4 11.1%
 9.0% 24 3
 3 IGA 0 0 24 NAVIGATE
 IGA 1 IGA 2



ECLIPSE

N=514 N=534 0 4 100 mg 8
 0 1 2 3 4 300 mg 4
 44
 BSA 20%
 PASI 18 24% IGA
 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%) ^a	360 (70.0%)
12	48 PASI 75	452 (84.6%) ^b	412 (80.2%)
12	PASI 75	477 (89.3%) ^c	471 (91.6%)
12	PASI 90	369 (69.1%) ^c	391 (76.1%)
48	PASI 100	311 (58.2%) ^c	249 (48.4%)

^a p<0.001

^b p < 0.001

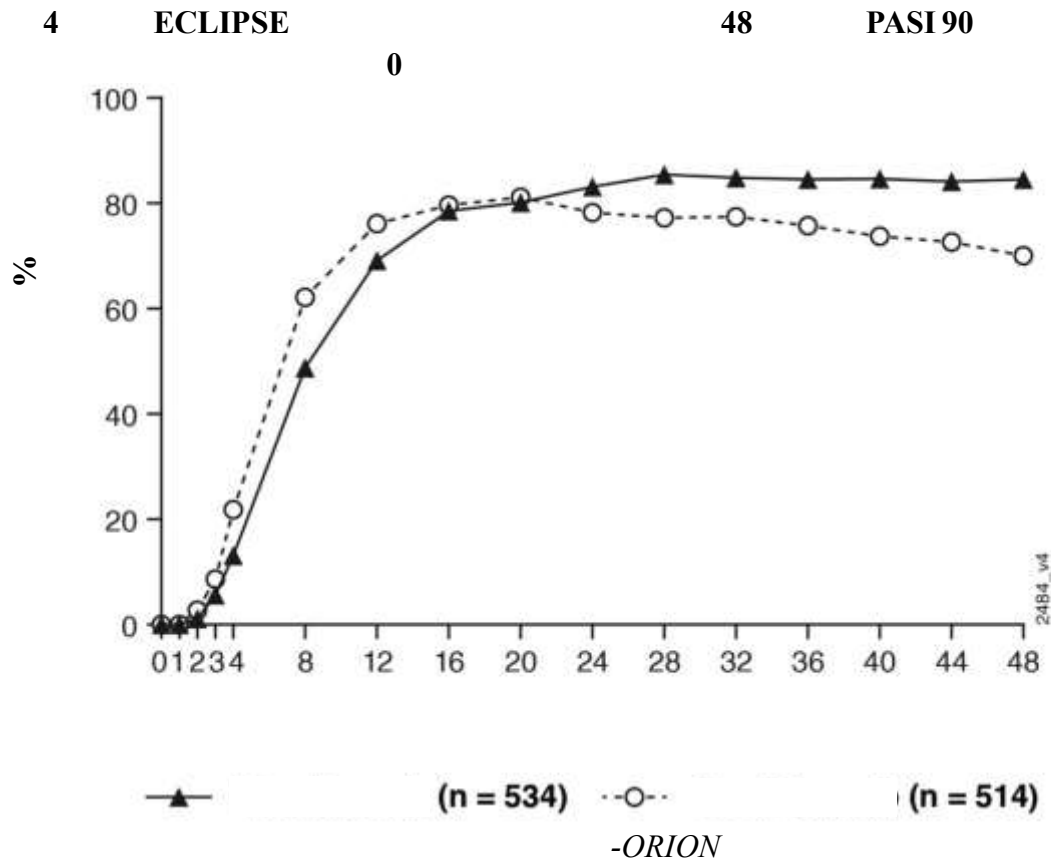
p=0.062

^c

48

PASI 90

4



ORION	-ORION										PK
	78										
	0	4	8					16	16		
	16	VOYAGE 1		VOYAGE 2						16	PASI
		IGAs	0	1					16		
90					16	IGAs	0				
	16	PASI 100									
		16	IGAs	0	1	PASI 90					
		80.6%	75.8%	p<0.001							
0%		16	IGAs	0							
	56.5%	0%	p<0.001		16	PASI 100					
	50.0%				0%	p 0.001					
	0	4	12								
								SIAQ	6		
10								0			
								12			
		9.18	10								
	9.24	10				12				8.43	
9.84											

23 p19 IL-23 IgG1λ IL-23 23 IL-

IL-17A IL-17F IL-22

2 mg/kg MRHD 60 100 mg/kg 25 mg/kg MRHD 15 2 mg/kg
mg/kg MRHD 6 30 1 3 10 mg/kg 50mg/kg
28 6 30 6

100 mg 5.5
± SD C_{max} 8.09 ± 3.68 mcg/mL
0 4 8 100 mg
20 ± SD III ± SD
1.15 ± 0.73 mcg/mL 1.23 ± 0.84 mcg/mL
100 mg
49%

V_z

7-10 L

IgG

IgG mAb

0.288 - 0.479 L/
17

CL

T_{1/2}

15-18

/

10 mg - 300 mg

C_{max} AUC

1384

70
65

65
65

4
CL/F

75

/

IgG mAb

IgG mAb

2 8

100 mg

1 mL
1 /

24

JS20201007

SJ20202004

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

19



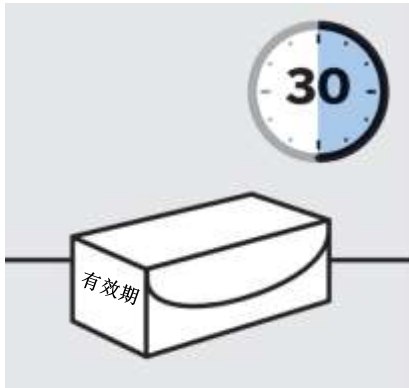
2 - 8 °C





- 1
 - 1
 - 1
 - 1
- 3

1.



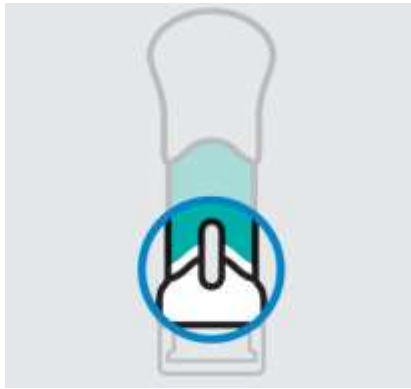
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“EXP”

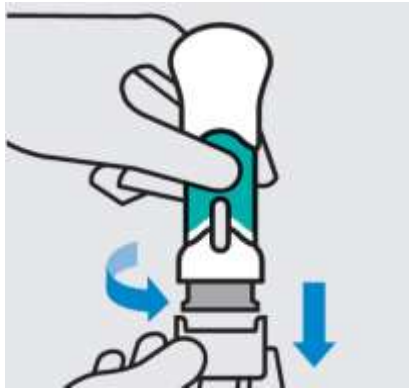


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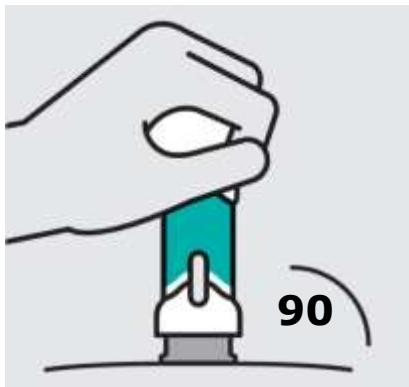
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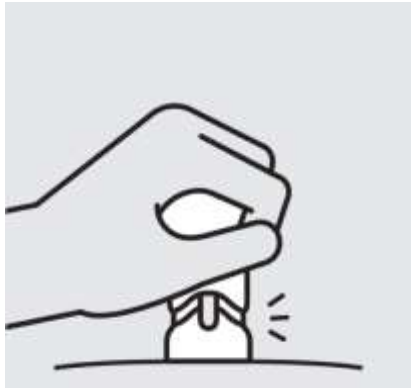
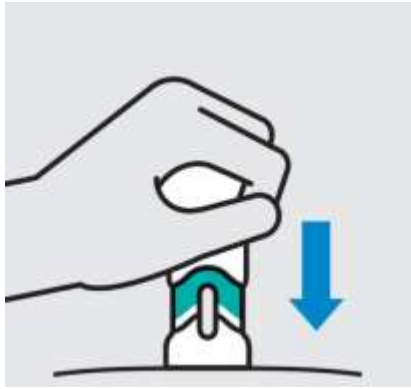
2.



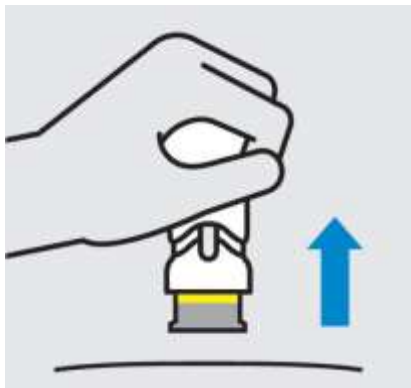
5



90



“ ”



3.

