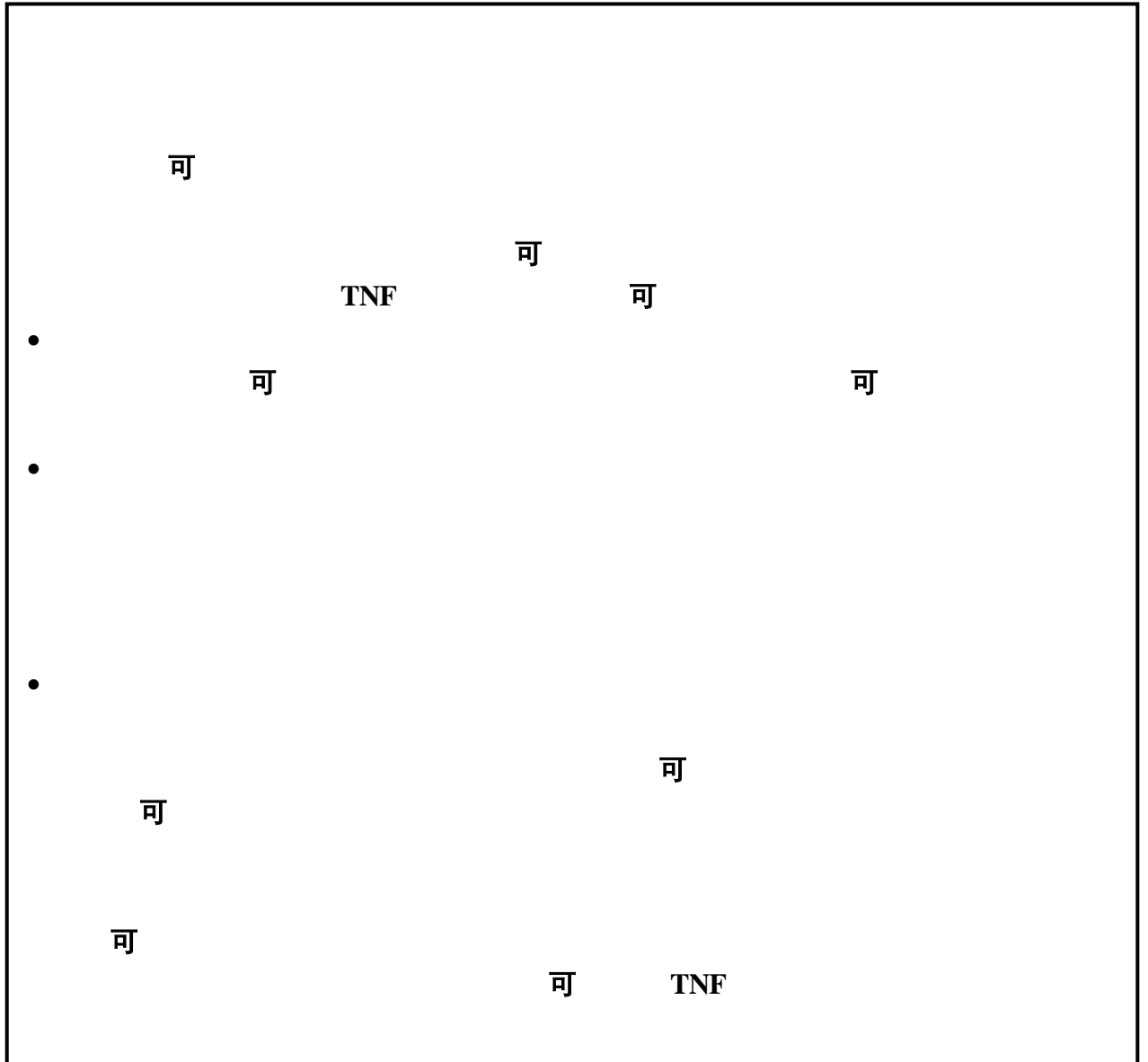


2020 08 13  
2021 06 21



® Simponi®  
Golimumab Injection  
Gelimu Dankang Zhusheye

L-

L-

80

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DMARDs

MTX

MTX

MTX

X

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50 mg(0.5 ml)/

50 mg 1

MTX

50 mg 1

12-14

3-

4

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- 2
- 2

• 30

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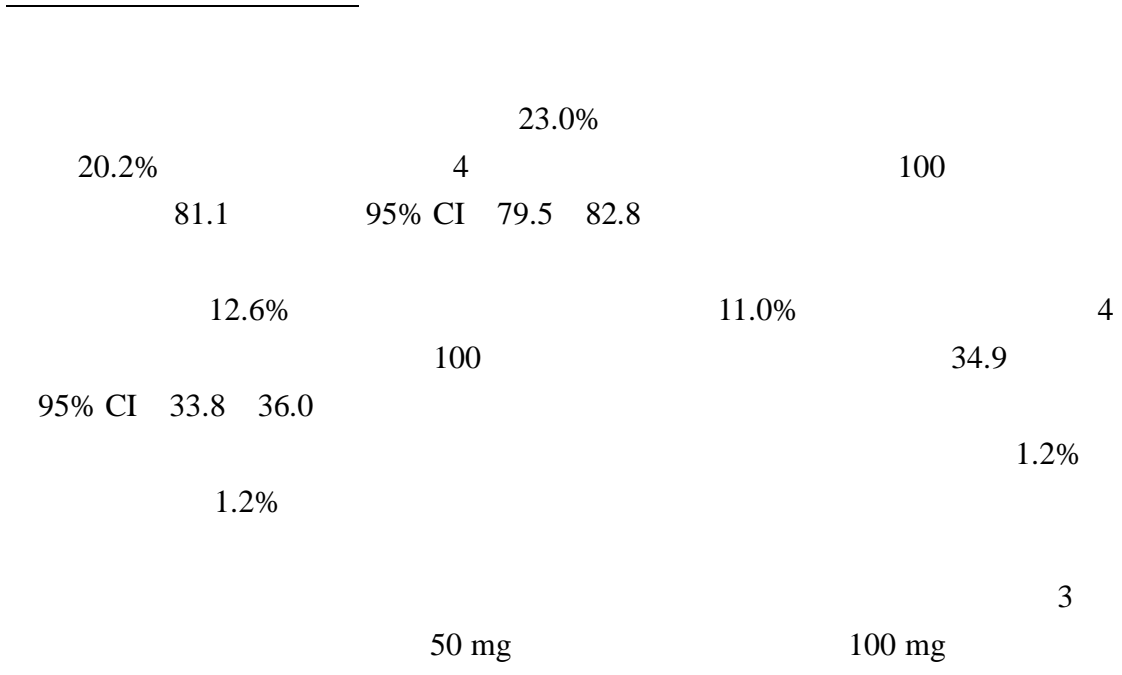
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12.6%

11.0%







3  
 50 mg  
 TNF  
 100 mg  
 GO-AFTER

4  
 3  
 50 mg  
 100 mg

<3× (ULN) 22.1%-27.4% ALT >1  
26.9% 10.6%  
5  
ALT

0.0% ALT ≥5×ULN 0.4%-0.9%  
5  
ALT ≥5×ULN ALT

1

2.0% 5.4%

II/III

3.5% 2.3% 1 ANA ≥1:160 1  
dsDNA dsDNA 1.1%

NYHA III/IV

—

TNF

“ ”

/

X

“ ”





HSTCL TNF T T  
AZA 6- 6-MP TNF  
AZA 6-MP  
TNF T  
IIb III

/

TNF Merkel  
TNF  
TNF  
TNF NYHA I/II

TNF  
Guillain-Barré /  
TNF

\_\_\_\_\_

\_\_\_\_\_ TNF

TNF

\_\_\_\_\_ TNF

ANA

\_\_\_\_\_ TNF

\_\_\_\_\_ TNF

TNF

\_\_\_\_\_ TNF

TNF

\_\_\_\_\_

\_\_\_\_\_ DMARDs

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

TNF

III

B  
2

MTX

MTX

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

6

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TNF

/

6

TNF

6

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\_\_\_\_\_  
P450

TNF□

CYP450

CYP450

CYP450

5

10 mg/kg

100 kg

1000 mg

1500

≥18

3

ACR

4

4

4

GO-FORWARD 444 15 mg/  
MTX TNF

+MTX 50 mg+MTX 100 mg+MTX

100 mg+ 24 +MTX

50 mg+MTX 52

GO-AFTER 1 TNF

445 TNF

58% 13% /

29% 50 mg 100  
mg MTX SSZ /

HCQ DMARD

GO-BEFORE MTX TNF

637 +MTX 50 mg+MTX

100 mg+MTX 100 mg+ 52

+MTX 1

50 mg+MTX

GO-FORWARD 14 ACR 20

24 HAQ

GO-AFTER 14 ACR 20

GO-BEFORE 24 ACR 50

52 van der Heijde- modified Sharp(vdH-S)

GO-FORWARD GO-BEFORE 104

GO-AFTER 24 50 mg 100 mg MTX

---

2 GO-FORWARD GO-AFTER GO-BEFORE 50  
mg 14 24 52 ACR

4

GO-FORWARD 89 50 mg+MTX

48 104 48 40

104 ACR 20 33 104 ACR 50 24

104 ACR 70

104 256 ACR 20 ACR 50 ACR 70

GO-AFTER ACR 20

1

TNF

**2 GO-FORWARD GO-AFTER GO-BEFORE**

	GO-FORWARD		GO-AFTER		GO-BEFORE	
	MTX		1 TNF		MTX	
	+ MTX	50 mg + MTX		50 mg	+ MTX	50 mg + MTX
n <sup>a</sup>	133	89	150	147	160	159
%						
<b>ACR 20</b>						
14	33%	55%*	18%	35%*	NA	NA
24	28%	60%*	16%	31% p = 0.002	49%	62%
52	NA	NA	NA	NA	52%	60%
<b>ACR 50</b>						
14	10%	35%*	7%	15% p = 0.021	NA	NA
24	14%	37%*	4%	16%*	29%	40%
52	NA	NA	NA	NA	36%	42%



GO-BEFORE 6  
 ACR 70 52 50 mg+MTX 15%  
 +MTX 7% p=0.018  
 50 mg+MTX 159 96 104  
 85 66 53 104 ACR 20/50/70  
 104 256 ACR  
 20 ACR 50 ACR 70

GO-BEFORE vdH-S /  
 52 3 50 mg  
 vdH-S ≤0  
 p=0.003 104 52  
 104  
 256

**3 GO-BEFORE 52 vdH-S**  
**SD**

	+MTX	50 mg+MTX
n <sup>a</sup>	160	159
	19.7 (35.4)	18.7 (32.4)
	1.4 (4.6)	0.7 (5.2)*
	11.3 (18.6)	10.8 (17.4)
	0.7 (2.8)	0.5 (2.1)
<b>JSN</b>		
	8.4 (17.8)	7.9 (16.1)
	0.6 (2.3)	0.2 (2.0)**

<sup>a</sup> n

\* p = 0.015

\*\* p = 0.044

GO-FORWARD GO-AFTER HAQ DI  
 24 HAQ DI

HAQ DI 104 256

HAQ DI  
GO-FORWARD 24 SF-36

104 SF-36

256 SF-36  
GO-AFTER - (FACIT-F) 104

GO-FORWARD  
(FACIT-F)

GO-RAISE  
356

[ 0~10cm Bath BASDAI  
≥4 VAS ≥4] TNF NSAID

DMARD 4

100 mg DMARD MTX SSZ / HCQ  
14 ASAS 20  
24

24 50 mg 100 mg  
4 50 mg

**4 GO-RAISE**

		50 mg*
n <sup>a</sup>	78	138
%		
<b>ASAS 20</b>		
14	22%	59%
24	23%	56%
<b>ASAS 40</b>		
14	15%	45%
24	15%	44%
<b>ASAS 5/6</b>		
14	8%	50%
24	13%	49%

\*  
a n p ≤ 0.001

ASAS 20 14 ASAS 40 24 p ≤ 0.017 BASDAI 50 24 BASDAI 70 256 BASDAI 90 4  
HLA-B27 14 CRP 24 DMARD MTX SSZ / HCQ BASDAI ASAS 20  
14 24 BASFI 14 24 SF-36  
24 256  
105/2062 III 52 5% (EIA)  
MTX 3% 41/1235 8% 64/827

TNFα TNFα TNFα TNFα  
E- VCAM-1 ICAM-1  
IL-6 IL-8 G-CSF GM-CSF

TNF $\alpha$   
-  
50mg/kg/  
MRHD 360 2

50mg/kg/  
860 310  
6

IgG 1/400  
IgG IgG 6  
6 6

(T<sub>max</sub>) 2-6  
(C<sub>max</sub>)  $\pm$  50 mg  
AUC<sub>inf</sub> 3.2 $\pm$ 1.4  $\mu$ g/mL  
53%

0.1 10.0mg/kg

58-126 mL/kg

0.1 10.0mg/kg

4.9 6.7 mL/kg/

2

0.1~10.0 mg/kg

50~400 mg

2~8°C

1

0.5 mL

1 /

24

JS20200026

SJ20202003

Janssen Biologics B.V.  
Einsteinweg 101, 2333 CB Leiden,

Cilag AG  
Hochstrasse 201, CH-8200 Schaffhausen,

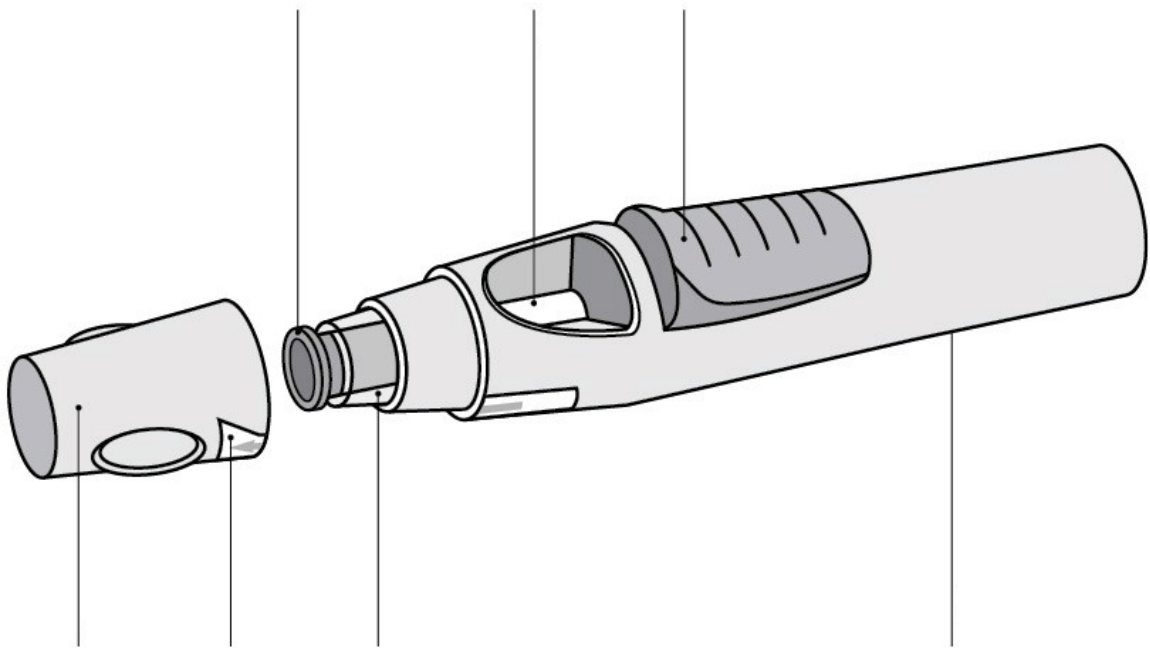
19

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

# Simponi

- 1.
- 2.
- 3.
- 4.

1 "SmartJect"



1

- 1.
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o

50 mg

50 mg

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“EXP”

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( 2)

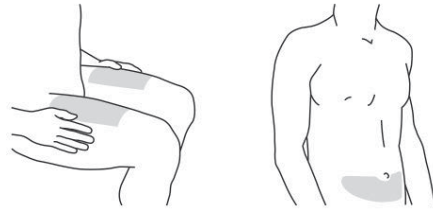
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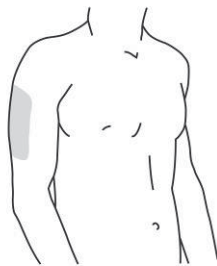


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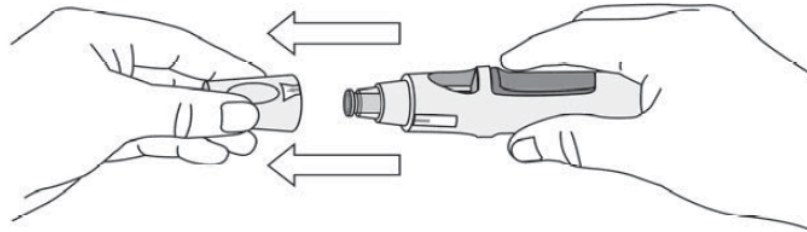
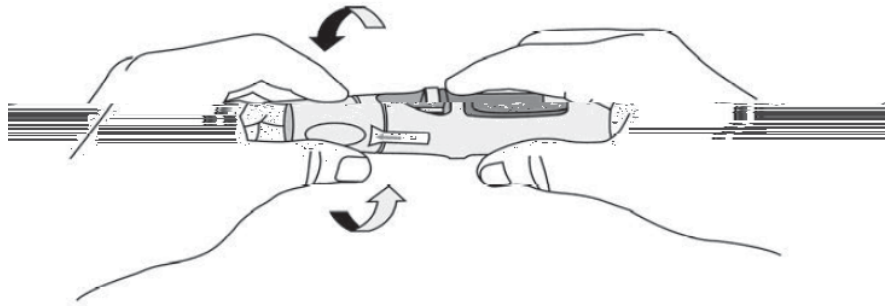
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5 6

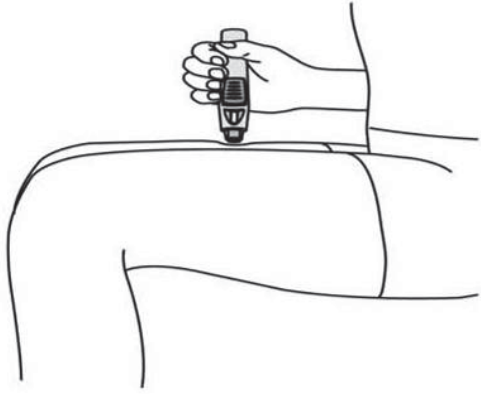
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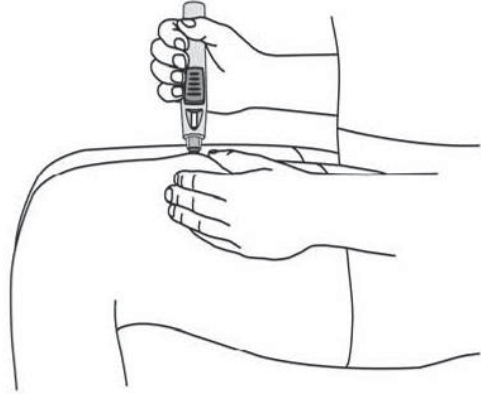
5a  
5b

90

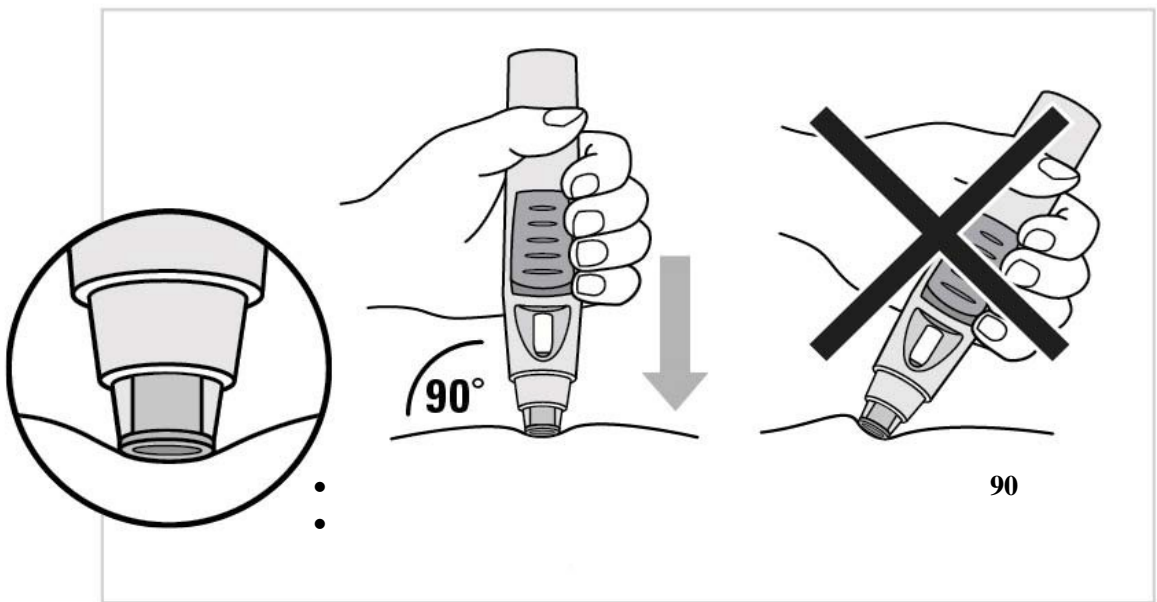
6



5a



5b

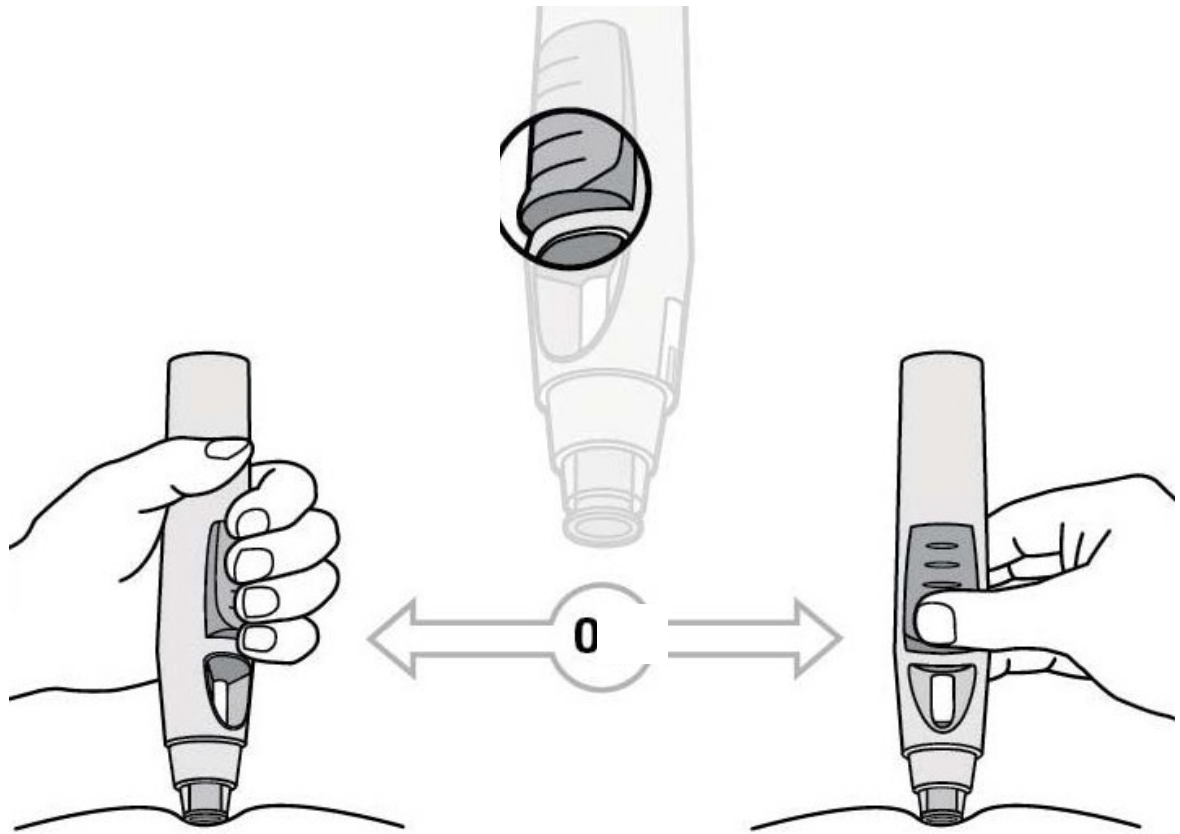


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3-6

15

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“ ”

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“ ”

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15

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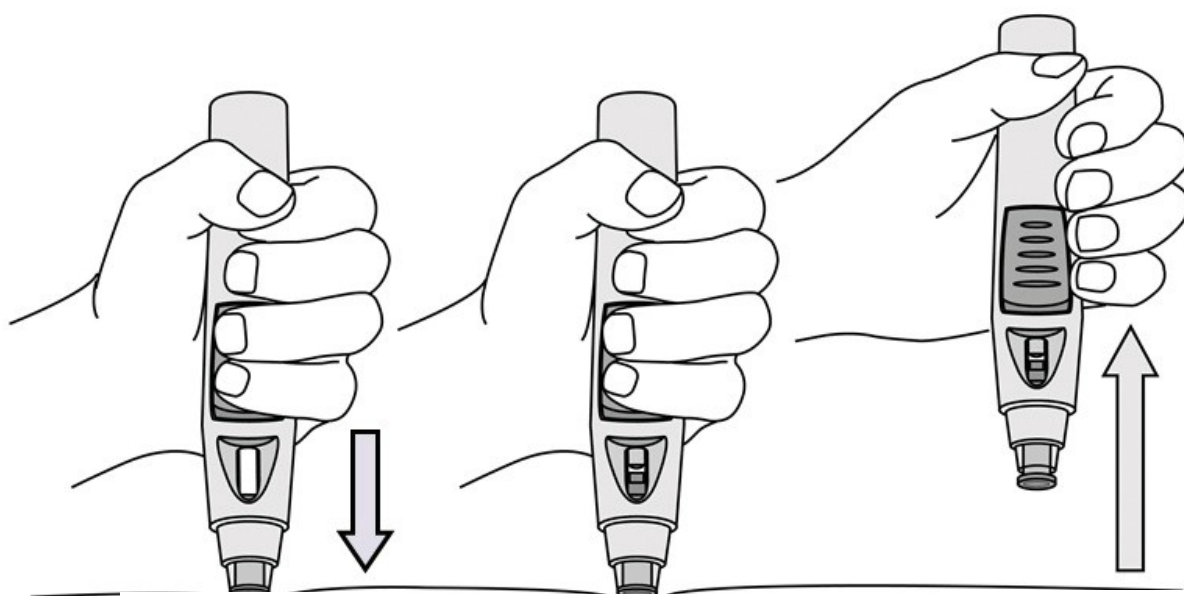


图 8

4.

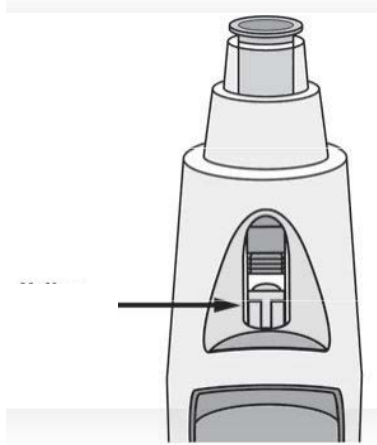
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