0.6%
8.3% 17/204
8.6% 16/185 5.3% 1/19
8.4% 77/920
2.3%
11/482 1.9% 11/590
2.6% 7/269
171 4-17 15.8 27/171
5/85 5.9 25.6 22/86 2-4 4 15kg
7 1/15
0.8mg/kg 5/38 13
3.3%

I~V 24
11.9% 8.1%
3441 2

III 4~104 ALT ≥3x ULN
3.7% 1.6%
III 12~24 ALT ≥3x ULN 1.8%
1.8%

TNFα IL-6 CYP450
CYP450 CYP450

药物过量

10mg/kg 15

临床试验

3000
120
RA I 271 18
12.5 25mg 10mg 10 25mg
20 40 80mg 24
RA II 544 18
20 40mg 26 26
RA III 619 18 12.5 25mg
10mg 3 52 2 20mg 52
3 40mg 52 457 40mg MTX
10
RA IV 636 18
28
/ 40mg 24
RA V 799 9

40mg 104
RA I II III IV 24 26 ACR20 V 52 ACR50
III V 52 X III
I II III ACR20 50 70 5 40mg
5 ACR

RA I~ε ч ˍ ϟ Y 40m̃ Ƀ f " |

RA I | ц # ḍ " Ʊ

40mg PASI 27.7 DLQI
14.5 PGA " " 63.8% " " 32.5% " " 3.8%
40mg 12 PASI75 77.8% 11.5% P 0.001
PGA PASI90 PASI100 DLQI SF-36
24
24

114 4 PGA ≥4 >20
BSA >10 BSA / PASI≥20 ≥10

0.8mg/kg(40mg) 0.4mg/kg(20mg) (MTX)0.1-0.4mg/kg)
(25mg), 16 0.4mg/kg MTX 0.8mg/kg (e.g.,PASI75)
14 16

PASI 75 PGA 36 PGA 2 16
0.8mg/kg PASI 75 78.9 15/19 PGA
52.6 10/19
PASI75 PGA 52

1500 CDAI ≥220 ≤450
/ 80%
-CD I CLASSIC I CD II GAIN CDAI<150 CD I 299 TNF
0 2 0 160mg 2 80mg 0 80mg 2 40mg
0 40mg 2 20mg CD II 325 0 160mg 2
80mg
CD III CHARM CD III 854 0 80mg 2 40mg 4
56 40mg 40mg 4 CDAI ≥70
8
15 CD I CD II
15

RA I~ε ч ˍ ϟ Y 40m̃ Ƀ f " |

CD III 4 58% 499/854 4 48% TNF
16 TNF
56
16

RA I | ц # ḍ " Ʊ

° Ů S ‐ r ‐ |

4 43% 12 30% 4
12 12
CD I 276 117 CD II III 777 272 3 88
189 102 233 CR-100
CD I CD II 4 80/40mg 160/80mg IBDQ
CD III 26 56

205 C ≥ 3 mg/L CDAI ≥ 220 ≤ 450
/ TNF
CDAI 273 30.7% 61.5% 1:1 0
160 mg 2 80 mg 4 6 40 mg 0 2 4 160 mg 6 80 mg
8 40 mg 24 12 80mg
4 CDAI < 150 37.3% vs.
6.8% P < 0.001 8 CDAI ≥ 70 64.6% 93/144 26
62.8% 26
26

<40kg ≥40kg 192 6 17 6 17
PCDAI 30
/
≥40 kg 0 160 mg 2 80 mg
< 40kg 80mg 40mg
4 1:1 17
17

26 PCDAI ≤10
18 PCDAI 15 19
18

19

26 52
IMPACT III
CD 100 n=100 5 50 PCDAI,
74.0% 37/50 92.0% 46/50

药理毒理

TNF TNF p55 p75 TNF
TNF ELAM-1 VCAM-1 ICAM-1
0.1~0.2nM

- / 20 97 100mg/kg

药代动力学

40mg 5 40mg
64% 0.25 10 mg/kg 0.5mg/kg(~40mg)
11 15ml/ (Vss) 5~6 2
31~96%
40mg 5μg/ml 8~9μg/ml
20 40 80mg
40mg 5μg/ml
0 160mg 2 80mg 12μg/ml
40mg 7 g/ml

24 40mg
80mg 7 4μg/ml 8μg/ml 7~28ml/ 6~21ml/
5~8L 6~10L 1.4 2

4-17 JIA 24mg/m² 40mg
20 48 5.6±5.6μg/ml 102 CV) 10.9±5.2μg/ml 47.7 CV
2-4 4 4 15kg JIA 24 mg/m²
6.0±6.1μg/ml(101 CV) 7.9±5.6μg/ml(71.2 CV)
0.8 mg/kg 40mg ±SD 7.4±5.8μg/ml 79% CV
40kg 0 2 160/80mg 80/40mg
4 1:1 40/20mg) 20/10mg) 4
±SD ≥40 kg 160/80 mg 15.7±6.6 g/mL, < 40 kg 80/40 mg 10.6±6.1 g/mL
52 ±SD 9.5±5.6 g/mL 3.5±2.2 g/mL 52
±SD 52 15.3±11.4 g/mL 40/20mg) 6.7±3.5 g/mL 20/10mg

JIA pJIA ERA PedACR 50 - PedACR 50
(EC50) 3μg/ml (95% CI:1-6μg/ml)
PASI 75 PGA - PASI 75 PGA /
EC50 4.5μg/ml (95% CI 0.4-47.6 1.9-10.5)

1300 AAA
AAA

贮 藏

2~8
2~8 ≤25 14
2~8 14 25

包 装

20mg
0.4ml
1 /

有 效 期 18

执行标准 :YBS00282021

批准文号 S20217001

上市许可持有人

11 A6
510530
020-32203220
020-32203220，400-9998703

生产企业

155
511356
020-32969891
020-32203220，400-9998703