Adalimumab

[IHUMR] Humira 40mg Solution for Injection 40mg/0.4mL ATC Code: L04AB04

中文名: (筆型)復邁注射劑 《艾伯維藥品》

適應症: 成人適應症:類風濕性關節炎。乾癬性關節炎。僵直性脊椎炎。克隆氏症。乾

癬。潰瘍性結腸炎。腸道貝西氏症。化膿性汗腺炎。葡萄膜炎。 小兒適應症:幼年型自發性多關節炎。克隆氏症。 葡萄膜炎。

藥理分類: Antirheumatic, Disease Modifying; Monoclonal Antibody; Tumor Necrosis

Factor (TNF) Blocking Agent.

用法用量: Administration:

SubQ: injection at separate sites in the thigh or lower abdomen (avoiding areas within 2 inches of navel); rotate injection sites.

Indications and dosage:

Adult:

Ankylosing spondylitis:

40 mg every other week (may continue methotrexate, other nonbiologic DMARDS, corticosteroids, NSAIDs and/or analgesics).

Psoriatic arthritis:

40 mg every other week (may continue methotrexate, other nonbiologic DMARDS, corticosteroids, NSAIDs and/or analgesics).

Rheumatoid arthritis:

40 mg every other week (may continue methotrexate, other nonbiologic DMARDS, corticosteroids, NSAIDs, and/or analgesics); patients not taking concomitant methotrexate may increase dose to 40 mg every week.

Crohn disease:

Initial: 160 mg (given on day 1 or split and given over 2 consecutive days), then 80 mg 2 weeks later (day 15).

Maintenance: 40 mg every other week beginning day 29. Note: Some patients may require 40 mg every week as maintenance therapy.

Plaque psoriasis:

Initial: 80 mg as a single dose.

Maintenance: 40 mg every other week beginning 1 week after initial dose.

Ulcerative colitis:

Initial: 160 mg (given on day 1 or split and given over 2 consecutive days), then 80 mg 2 weeks later (day 15).

Maintenance: 40 mg every other week beginning day 29. Note: Only continue maintenance dose in patients demonstrating clinical remission by 8 weeks (day 57) of therapy.

Hidradenitis suppurativa:

Initial: 160 mg (given on day 1 or split and given over 2 consecutive days), then 80 mg 2 weeks later (day 15).

Maintenance: 40 mg every week beginning day 29.

Uveitis (Humira only):

Initial: 80 mg as a single dose.

Maintenance: 40 mg every other week beginning 1 week after initial dose.

Behcet's syndrome:

Initial: 160 mg (given on day 1 or split and given over 2 consecutive days), then 80 mg 2 weeks later (day 15).

Maintenance: 40 mg every other week beginning day 29.

Children:

Crohn disease: Children ≥6 years and Adolescents:

17 kg to <40 kg:

Initial: 80 mg divided into 2 injections (40 mg each) on day 1, then 40 mg administered 2 weeks later (day 15);

maintenance: 20 mg every other week, begin on day 29. Patients who continue to experience flares after 12 weeks of therapy may benefit from weekly dosing. ≥40 kg:

Initial: 160 mg divided into 4 injections (40 mg each, administered on one day or as 2 injections per day over 2 consecutive days), then 80 mg (divided into 2 injections [40 mg each] administered on one day) 2 weeks later (day 15); **maintenance:** 40 mg every other week, begin on day 29. Patients who continue to experience flares after 12 weeks of therapy may benefit from weekly dosing.

Uveitis:

Children ≥2 years and Adolescents:

Initial: No data about use of initial (loading) dose available under 6 years old

<30 kg: 40 mg as a single dose.

 \geq 30 kg: 80 mg as a single dose.

Maintenance: beginning 1 week after initial dose.

< 30 kg: 20 mg every other week, continue methotrexate

≥30 kg: 40 mg every other week, continue methotrexate.

Juvenile idiopathic arthritis:

Children ≥2 years and Adolescents:

 $10 \text{ kg} \sim 15 \text{ kg}$: 10 mg every other week

 $15 \text{ kg} \sim < 30 \text{ kg}$: 20 mg every other week

 \geq 30 kg : 40 mg every other week

May continue methotrexate, glucocorticoids, NSAIDs, and analgesics.

不良反應: 呼吸道感染、系統性感染(包括敗血症、念珠菌症以及流行性感冒)、腸道感染 (包括病毒性腸胃炎)、皮膚及軟組織感染、敏感、過敏症、焦慮、失眠、腹痛、 噁心嘔吐、肝酵素上升、紅疹、肌肉骨骼疼痛、注射部位反應、頭痛。

- 注意事項: 1. 注射部位包括大腿或腹部。應輪換注射部位。絕不可於敏感、瘀青、發紅或變硬的皮膚給予新一次的注射。
 - 2. 治療期間較容易受到嚴重黴菌感染。若病人產生發燒、倦怠、體重減輕、出汗、咳嗽、呼吸困難、或其他嚴重的全身性疾病(有/無伴隨休克)時,應立即尋求醫療照顧以進行診斷評估。
 - 3. 除了活體疫苗以外,使用 Humira 的病人可以同時接受疫苗的施打。
- 懷孕期: 應採取適當的避孕措施避免懷孕,並且於最後一次 Humira 治療之後繼續 避孕至少 5 個月。
 - 如確實有必要,可考慮在懷孕期間使用 Humira。
- 哺乳期: adalimumab 會分泌於乳汁中,人類乳汁中 adalimumab 濃度為母體血清濃度的 0.1%至 1%,且生體可用率不佳。預期對哺乳餵養的新生兒/嬰兒沒有影響。因此,Humira 可以在哺乳期間使用。
- 健保規定: 一、類風濕關節炎、僵直性脊椎炎、乾癬、乾癬性周邊關節炎、乾癬性脊椎病變與克隆氏症病患使用...adalimumab......等生物製劑皮下注射劑,經事前審查核准後,在醫師指導下,至多可攜回四週之使用量。(93/8/1、109/10/1)二、8.2.4.1:兒童治療部分。8.2.4.2:成人治療部分。8.2.4.3:用於僵直性脊椎炎治療部分。8.2.4.4:用於乾癬性周邊關節炎治療部分。8.2.4.5:用於乾癬性脊椎病變治療部分。8.2.4.6:用於乾癬治療部分。8.2.4.7.1:用於克隆氏症成人治療部分。8.2.4.7.2:用於克隆氏症兒童治療部分。8.2.4.9.1:用於潰瘍性結腸炎成人治療部分。8.2.4.10:用於小兒葡萄膜炎治療(109/09/1)。詳健保規定。