[Notes to editors]

1. Summary of Product Charateristics

[Information being added is indicated by underlining]

1) Brand name:

HUMIRA® for Subcutaneous Injection 20 mg syringe 0.4 mL
HUMIRA® for Subcutaneous Injection 40 mg syringe 0.8 mL
HUMIRA® for Subcutaneous Injection 40 mg syringe 0.4 mL *
HUMIRA® for Subcutaneous Injection 80 mg syringe 0.8 mL *
*Prelaunched

2) Generic name:

Adalimumab (recombinant)

3) Indications:

HUMIRA for Subcutaneous Injection 20 mg syringe 0.4 mL
HUMIRA for Subcutaneous Injection 40 mg syringe 0.8 mL
HUMIRA for Subcutaneous Injection 40 mg syringe 0.4 mL

Patients who have had an inadequate response to conventional therapy for the following disease

Juvenile idiopathic arthritis with active polyarthritis

HUMIRA for Subcutaneous Injection 40 mg syringe 0.8 mL
HUMIRA for Subcutaneous Injection 40 mg syringe 0.4mL
HUMIRA for Subcutaneous Injection 80 mg syringe 0.8 mL

Rheumatoid arthritis (including inhibition of the progression of structural damage)

Patients who have had an inadequate response to conventional therapy for the following diseases

Plaque psoriasis and Arthritic psoriasis
Ankylosing Spondylitis
Intestinal Behcet's disease
<u>Non-infectious intermediate uveitis, posterior uveitis or panuveitis</u>

Induction and maintenance therapy for moderate to severely active Crohn's disease (administer HUMIRA to patients who have had an inadequate response to conventional therapy.)

Treatment of moderate to severe ulcerative colitis (administer HUMIRA to patients who have had an inadequate response to conventional therapy)

4) Dosage and administration:

HUMIRA for Subcutaneous Injection 20 mg syringe 0.4 mL
HUMIRA for Subcutaneous Injection 40 mg syringe 0.8 mL
HUMIRA for Subcutaneous Injection 40 mg syringe 0.4 mL

JdzØŜyʃfŜ ʎŘʎ2LJaűKʎc aǊűKǊʎűʎă ǿʎűK acűʎØŜ LJ2fèaǊűKǊʎűʎă

N2ǊƳaffè űKŜ Ř2ăŜ 2Ŧ aŘafʎƳdzƳab óƎŜyŜűʎc ǊŜc2Ƴbʎyaűʎ2yű Ŧ2Ǌ ƨdzØŜyʃfŜ ʎŘʎ2LJaűKʎc aǊűKǊʎűʎă LJaűʎŜyűă ǿK2 ǿŜʎƎK 2ØŜǊ мр ƪƎ bdzű fŜăă űKayʃ ол ƪƎ ʎă нл ƳƎ aŘƳʎyʃăűŜǊŜŘ ŜØŜǊè 2űKŜǊ ǿŜŜƪ óŜ2ǿű ayŘ Ŧ2Ǌ LJaűʎŜyűă ǿŜʎƎKʎyƎ ол ƪƎ 2Ǌ Ƴ2ǊŜ ʎă пл ƳƎ aŘƳʎyʃăűŜǊŜŘ Ŝ2ǿ aă ădzbcdzűayŜ2dză ʎyƨŜcűʎ2yΦ

HUMIRA for Subcutaneous Injection 40mg syringe 0.8 mL
HUMIRA for Subcutaneous Injection 40mg syringe 0.4 mL
HUMIRA for Subcutaneous Injection 80mg syringe 0.8 mL

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[illegible]

[illegible]

[illegible]

[illegible]

Precautions for Use (The related part to non-infectious uveitis)
HUMIRA should be administered only when clinical symptoms clearly attributed to the disease remained in the previous treatments, despite the proper treatment with conventional therapies (cyclosporine and etc. in the case of uveitis secondary to Behcet's disease, or oral steroids and etc. in the case of other non-infectious uveitis).

Adverse Reactions
Major adverse reactions included nasopharyngitis (30.0%), injection site erythema (9.7%), injection site reaction (8.6%), rash (7.6%), upper respiratory tract infection (6.4%).

3. About VISUAL-I, II, III
VISUAL-I and II investigated active and controlled non-infectious intermediate, posterior and panuveitis. These two trials were double-blind, randomized and placebo-controlled. VISUAL-I and VISUAL-II clinical trials were randomized 1:1 and patients treated with HUMIRA received an 80 mg baseline loading dose followed by 40 mg given by subcutaneous injection at week 1, followed by 40 mg every other week for up

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