Patient name: _____

Physician name: _____

Date: _____

Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)

It should take you no more than a minute or two to complete this questionnaire. Your responses will help your doctor assess how active your ankylosing spondylitis (AS) is, and will let him or her track changes in your condition over time.

Please mark an X in the box that represents how you feel (your answers should apply to the past week only). Your doctor will add up the scores.

SCORE

1. How would you describe the overall level of fatigue/tiredness you have experienced?

0 1 2 3 4 5 6 7 8 9 10

None — Very severe

0

2. How would you describe the overall level of AS **neck**, **back** or **hip** pain you have had?

0 1 2 3 4 5 6 7 8 9 10

None — Very severe

0

3. How would you describe the overall level of pain/swelling in joints **other than** neck, back or hips you have had?

0 1 2 3 4 5 6 7 8 9 10

None — Very severe

0

4. How would you describe the overall level of discomfort you have had from any areas tender to touch or pressure?

0 1 2 3 4 5 6 7 8 9 10

None — Very severe

0

Total of Q1 to Q4 = A 0

5. How would you describe the overall level of morning stiffness you have had from the time you wake up?

0 1 2 3 4 5 6 7 8 9 10

None — Very severe

0

6. How long does your morning stiffness last from the time you wake up?

0 1 2 3 4 5 6 7 8 9 10

0 hour — ½ hour — 1 hour — 1 ½ hours — 2 hours +

0

Last BASDAI score

Absolute change 0.00

% change NaN

Average of Q5 + Q6 = B 0

Total score A + B 0

(A + B) ÷ 5 = Total BASDAI score 0

– Adapted from Garrett S *et al*.[1]

HUMIRA. Power to Fight AS

HUMIRA has 15 years of clinical experience worldwide combined across all indications[2]

- >1.6 million patient-years of exposure[2]
- >670,000 patients currently treated worldwide[2]
- 71 clinical trials with over 23,000 patients[2]
- 9 years in Canadian practice[3]
- 7 indications[3]
- Available in 89 countries[2]

HUMIRA® adalimumab | 15 years of clinical experience worldwide

Indicated in the inflammatory conditions:[3†] RA | JIA | PsA | AS | Adult CD | Ped CD | Ps

HUMIRA is indicated for:

- Reducing the signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA). Can be used alone or in combination with methotrexate (MTX) or other disease-modifying antirheumatic drugs (DMARDs).
  When used as first-line treatment in recently diagnosed patients who have not been previously treated with MTX, HUMIRA should be given in combination with MTX. Can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is contraindicated.
- In combination with MTX, reducing the signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients 4 to 17 years of age who have had an inadequate response to one or more DMARDs. Can be used as monotherapy in case of intolerance to MTX or when continued treatment with MTX is not appropriate. HUMIRA has not been studied in children aged less than 4 years.
- Reducing the signs and symptoms in patients with active ankylosing spondylitis (AS) who have had an inadequate response to conventional therapy.
- Reducing the signs and symptoms of active arthritis and inhibiting the progression of structural damage and improving the physical function in adult psoriatic arthritis (PsA) patients. Can be used in combination with MTX in patients who do not respond adequately to MTX alone.
- Reducing the signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response to conventional therapy, including corticosteroids and/or immunosuppressants. HUMIRA is indicated for reducing the signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.
- Reducing the signs and symptoms and inducing and maintaining clinical remission in pediatric patients 13 to 17 years of age weighing ≥ 40 kg with severely active Crohn's disease and/or who have had an inadequate response or were intolerant to conventional therapy (a corticosteroid and/or aminosalicylate and/or an immunosuppressant) and/or a tumour necrosis factor alpha antagonist.
- Treatment of adult patients with chronic moderate to severe psoriasis (Ps) who are candidates for systemic therapy. For patients with chronic moderate plaque psoriasis, HUMIRA should be used after phototherapy has been shown to be ineffective or inappropriate.

Clinical use

Safety and effectiveness in pediatric patients with polyarticular JIA less than 4 years of age have not been established. Limited data are available for treatment with HUMIRA in children weighing <15 kg. Clinical trial data for patients aged 4 to 6 years with polyarticular JIA are limited.

The safety and efficacy of HUMIRA were authorised in pediatric patients 13 to 17 years of age weighing ≥40 kg with severely active Crohn's disease and/or who have had an inadequate response or were intolerant to conventional therapy.

Contraindications

- Severe infections such as sepsis, tuberculosis and opportunistic infections.
- Moderate to severe heart failure (NYHA class III/IV).

Most serious warnings and precautions

Hepatosplenic T-Cell Lymphoma (HSTCL): Very rare post-marketing reports of HSTCL, a rare aggressive lymphoma that is often fatal, have been reported. Most of the patients had prior infliximab therapy as well as concomitant azathioprine or 6-mercaptopurine use for Crohn's disease. The potential risk with the combination of azathioprine or 6-mercaptopurine and HUMIRA should be carefully considered.

Infections: Serious infections have been reported. Hospitalization or fatal outcomes associated with infections have been reported. Many of the serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their underlying disease, could predispose them to infections. Treatment with HUMIRA should not be initiated in patients with active infections. In patients who have been exposed to tuberculosis, and patients who have traveled in areas of high risk of tuberculosis or endemic mycoses, the risks and benefits of treatment with HUMIRA should be considered prior to initiating therapy. As with other TNF blockers, patients should be monitored closely for infections (including tuberculosis) before, during and after treatment with HUMIRA. Administration of HUMIRA should be discontinued if a patient develops a serious infection or sepsis, and appropriate therapy should be initiated. Physicians should exercise caution when considering the use of HUMIRA in patients with a history of recurrent infection or with underlying conditions which may predispose them to infections, or patients who have resided in regions where tuberculosis and histoplasmosis are endemic.

Pediatric Malignancy: Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including HUMIRA.

Other relevant warnings and precautions

- Concurrent administration with other biologic DMARDs or other TNF antagonists not recommended
- Surgery: Close monitoring for infection required
- Patients with congestive heart failure: Cases of worsening congestive heart failure (CHF) and new onset CHF
- Hematologic events: Pancytopenia, including aplastic anemia, and medically significant cytopenia
- Hypersensitivity reactions, including anaphylaxis and latex allergic reactions
- Autoimmunity
- Immunosuppression
- Immunizations: Live vaccines must be avoided. It is recommended that pediatric patients, if possible, be brought up to date with all immunizations in agreement with current immunization guidelines prior to initiating HUMIRA therapy
- Infections: Tuberculosis (TB), (including reactivation and new onset of TB), opportunistic infections, (including invasive fungal infections), and hepatitis B virus reactivation
- Malignancies including lymphoma and non-lymphoma malignancy
- Neurological events: New onset or exacerbation of demyelinating disease
- Pregnant women: HUMIRA may cross the placenta; infants born to women treated with HUMIRA during pregnancy may be at increased risk for infection
- Nursing women: Breastfeeding is not recommended for at least five months after the last HUMIRA treatment
- Geriatrics: Higher incidence of infections and malignancies

For more information

Please consult the Product Monograph at http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece.

The Product Monograph is also available by calling at 1-888-703-3006.

† RA: rheumatoid arthritis; JIA: polyarticular juvenile idiopathic arthritis; AS: ankylosing spondylitis; PsA: psoriatic arthritis; CD: Crohn's disease; Ped CD: pediatric Crohn's disease; Ps: psoriasis

References: 1. Garrett S, Jenkinson T, Kennedy LG *et al.* A new approach to defining disease status in ankylosing spondylitis: The Bath Ankylosing Spondylitis Disease Activity Index. *J Rheumatol* 1994;21:2286-91. **2.** Data on file. AbbVie Corporation. **3.** HUMIRA Product Monograph. AbbVie Corporation. August 21, 2013.

This form should be filled out with a nurse.

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POWER TO FIGHT AS

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