PATIENT SUPPORT PROGRAM
Harmony™ By ORGANON

Enrollment Form

HADLIMA®
adalimumab injection

Tel: 1-866-556-5663 Fax: 1-866-240-4076
Email: info@harmonybyorganon.ca
Monday to Friday, 8 a.m. to 8 p.m. ET

Patient Information

First name | Last name

Gender M ☐ F ☐ | Date of birth (dd/mm/yyyy) _____

Do you have health insurance coverage? ☐ Private ☐ Public ☐ Both

Preferred phone | Alternate phone

Best time to reach you ☐ Morning ☐ Afternoon ☐ Evening

Leave a message ☐ Yes ☐ No

Email

Preferred language ☐ English ☐ French ☐ Other: _____

Address

City | Province | Postal code

DO YOU AGREE TO BE CONTACTED BY THE PROGRAM OR ORGANON'S AGENTS FOR MARKET RESEARCH PURPOSES AND STUDIES RELATED TO THE PATIENT SUPPORT PROGRAM?

☐ **YES** ☐ **NO**

Prescriber Information

Prescriber name

Phone | Fax

Email

Address

City | Province | Postal code

Preferred mode of communication ☐ Fax ☐ Email ☐ Phone

Other information/office stamp

By signing below, I hereby approve this patient to begin treatment with HADLIMA® immediately, unless otherwise advised (or indicated) before.

PRESCRIBER'S SIGNATURE

SEE FULL PRESCRIBER CONSENT TERMS ON REVERSE. PLEASE ENSURE YOU HAVE READ AND FULLY UNDERSTAND THE PRESCRIBER CONSENT TERMS.

Prescriber's signature _____ Date (dd/mm/yyyy) _____

Prescription Information

Diagnosis and Treatment

New to adalimumab? ☐ Yes ☐ No

If you do not approve this patient to begin treatment with HADLIMA® immediately, please provide reason (eg.: pending testing, training, etc.) and specify start date.

Tuberculosis **(TB)** screening:

☐ I confirm that TB testing has been completed for the above-named patient, and that he/she can start the treatment on HADLIMA®

I would like the HARMONY BY ORGANON™ Patient Support Program to:
☐ schedule TB QuantiFERON test ☐ schedule TB skin test ☐ not schedule

Adult patient with a diagnosis of:
☐ Rheumatoid arthritis **(RA)** ☐ Psoriatic arthritis **(PsA)** ☐ Ankylosing spondylitis **(AS)**
☐ **Recommended dose:** 40 mg administered every other week subcutaneously (sc).

Adult patient with a diagnosis of: ☐ Crohn's Disease **(CD)** ☐ Ulcerative Colitis **(UC)**
☐ **Starting dose (Week 0):** 160 mg administered sc. This can be given in one day (four 40 mg injections) or split over two consecutive days (two 40 mg injections each day).
☐ **Second dose (Week 2):** 80 mg administered sc, given as two 40 mg injections in one day.
☐ **Maintenance dose (Week 4+):** 40 mg administered sc every other week.

Adult patient with a diagnosis of: ☐ Hidradenitis Suppurativa **(HS)**
☐ **Starting dose (Week 0):** 160 mg administered sc. This can be given in one day (four 40 mg injections) or split over two consecutive days (two 40 mg injections each day).
☐ **Second dose (Week 2):** 80 mg administered sc, given as two 40 mg injections in one day.
☐ **Maintenance dose (Week 4+):** 40 mg administered sc every week.

Adult patient with a diagnosis of: ☐ Psoriasis **(PsO)** ☐ Uveitis
☐ **Starting dose (Week 0):** 80 mg administered sc, given as two 40 mg injections in one day.
☐ **Maintenance dose (Week 1+):** 40 mg administered sc every other week.

Adolescent patient 12 to 17 years of age weighing ≥30 kg with a diagnosis of:
☐ Hidradenitis Suppurativa **(HS*)**
Patient weight: _____
☐ **Starting dose (Week 0):** 80 mg administered sc, given as two 40 mg injections in one day.
☐ **Subsequent doses (Week 1+):** 40 mg administered sc every other week. (40 mg administered sc every week may be considered if inadequate response)

Pediatric patient ≥2 years of age weighing ≥30 kg with a diagnosis of:
☐ Polyarticular juvenile idiopathic arthritis **(JIA*)**
Patient weight: _____
☐ **Recommended dose:** 40 mg administered sc every other week.

Pediatric patient ≥2 years of age weighing ≥30 kg with a diagnosis of: ☐ Uveitis*
Patient weight: _____
☐ **Starting dose (Week 0):** Optional in patients ≥6 years of age weighing ≥30 kg. 80 mg administered sc, given as two 40 mg injections in one day.
☐ **Subsequent doses (Week 1+):** 40 mg administered sc every other week.

*The auto-injector and pre-filled syringe are not designed to deliver a portion of the full 40 mg dose and must not be used in pediatric patients who require <40 mg dose.

Format:
☐ Pre-filled auto-injector ☐ Pre-filled syringe

Duration of treatment:
☐ For 4 weeks ☐ Repeat X _____

PATIENT'S SIGNATURE OR LEGALLY AUTHORIZED REPRESENTATIVE'S SIGNATURE

SEE FULL PATIENT CONSENT TERMS ON REVERSE. PLEASE ENSURE YOU HAVE READ AND FULLY UNDERSTAND THE PATIENT CONSENT TERMS.

Patient's signature _____ Date (dd/mm/yyyy) _____

Prescriber's Disclosure and Consent

PRESCRIBER'S DISCLOSURE AND CONSENT: Please read the information included in the Patient Enrollment Consent section to obtain a full description of the HARMONY BY ORGANON™ **Program** and, if you agree, sign the form.

- I, the undersigned, have read the Terms and Conditions. I understand the services offered by the Program and I represent that (i) I have met with the patient and discussed the Program with him/her; (ii) the patient understands the Program; (iii) the patient is interested in enrolling in the Program; (iv) the patient has consented to me filling out the form and communicating it to the Program Administrator and, when applicable, to any third parties involved in the Program for purposes of enrollment in the Program or its administration (the "**Third Parties Involved**"); (v) the patient was explained that consent for the sharing of coded data with Organon is necessary for the management of the Program; and (vi) the patient agrees to be contacted by the Program Administrator and/or any Third Parties Involved whose services have been retained to initiate and manage his/her enrollment in the Program.
- I understand that, for the purposes of being provided relevant information related to the services offered to the patient, I may be reached using the contact information provided in the 'Prescriber Information' section above by Organon, the Program Administrator and/or any Third Parties Involved, or their agents.
- I understand that prescribing information may be used by the Program Administrator, Third Parties Involved or by Organon or its agents for statistical analysis and research purposes relevant for operational and business planning in a manner which will not allow my identification.
- I understand that my personal information, which I provided, as well as prescribing information that does not allow identifying my patient, may be shared with Organon or its agents for the purposes of the Program assessment, management and enhancement.
- I also consent to be reached, using the contact information provided in the 'Prescriber Information' section above, for the purpose of inquiring about my experience with the Program so that services may be improved, by Organon, the Program Administrator, the Third Parties Involved or their agents.
- I understand that I may request access to the information collected about me to ensure accuracy and correct any mistake or revoke this consent at any time by mailing, emailing or faxing a signed request to the Program Administrator (address: 1-1393 North Service Rd. East, Oakville, Ontario L6H 1A7; email: info@harmonybyorganon.ca and fax number: 1-866-240-4076).
- I, the undersigned, certify that my patient's condition is within the indications listed in the current product monograph and that the dosage is appropriate based on my clinical judgment.
- I have determined that it is appropriate for this patient to be trained in self-injection of HADLIMA® (adalimumab injection). The patient understands that he/she may only self-inject HADLIMA® (adalimumab injection) if he/she accepts to receive self-injection training.
- By providing the name and business coordinates of the Nurse, I represent that I have obtained his/her consent to do so for the purpose of the Program.
- I agree to the use and transfer of my name and coordinates to the appropriate public payors to assist with the transfer of my patient into the public program, where applicable.
- I, the undersigned, also agree to the disclosure of appropriate clinical documentation to controllers and auditors contracted by Organon for audit purposes, to the extent that such disclosure is in accordance with the Terms and Conditions.
- I understand that the Program can be terminated or modified at any time.

Patient Enrollment Form/Terms and Conditions of the Program

PLEASE READ THIS CONSENT FORM CAREFULLY BEFORE SIGNING

The objectives and purposes of the HARMONY BY ORGANON™ **Program** consist of offering free confidential patient-assistance services designed for patients who have been prescribed HADLIMA® (adalimumab injection). If eligible, you will be provided with reimbursement assistance, free drug and/or financial assistance, nursing support services, pharmacy, home or clinic delivery and/or injection support services and coordination/administration of laboratory testing. I understand that if my prescriber determines that it is appropriate for me, the HARMONY BY ORGANON™ Program may offer me self-injection training so that I may self-inject HADLIMA® (adalimumab injection). I understand that the Program can be terminated or modified at any time.

1. What type of personal information is collected and why?

The Program Administrator and, when applicable, any third parties involved in the Program enrollment process or its administration (the "**Third Parties Involved**") need to collect personal information to determine your eligibility for the Program, administer the Program, communicate with you and identify you (for example by asking you questions). The information included on this form will be submitted to either the Program Administrator or any Third Parties Involved by your healthcare provider on your behalf.

In addition, in some cases, your personal information (including financial and health information) may be collected from third parties such as your healthcare provider, health insurer, provincial public payer and your caregiver. For example:

- Your medical history and condition and other health information may be obtained from your healthcare provider for the purpose of determining your eligibility to enroll in the Program.
- Your health insurance and payment information may be collected from your health insurer for the purpose of assisting you with a reimbursement for which you are eligible.

2. How is your personal information shared?

Third parties assisting with the Program. Your personal information may be exchanged among the Program Administrator, the Third Parties Involved, their agents, your healthcare provider or health insurer, the provincial public payer, nurses, prescribers, pharmacists, the laboratory and your caregiver, when necessary to manage your participation in the Program. For example, your health insurance information may be shared by the Program Administrator or any Third Parties Involved with your insurance provider for the purposes of determining your eligibility for reimbursement.

Program sponsor. Organon, the sponsor of the Program, may receive: (i) coded information (personal information stripped of its direct identifiers such as your name, address, full date of birth or similar information linked to a secret code) necessary to manage patient enrollment as well as for operational and business planning; as well as (ii) aggregated information (personal information combined with the information of other Program participants without the possibility of identifying you) so that it can perform statistical analysis and identify trends in order to improve the Program. It may also receive your personal information, but only when required by law or in the following limited circumstances:

- a complaint is received in connection with the Program;
- a healthcare provider either has a special request that would require pre-authorization from Organon or has indicated special instructions on an enrollment form requiring Organon's involvement to coordinate the request;
- there is an adverse event and Organon needs to follow up with your healthcare provider.

3. Where is your personal information stored and how can you access it?

The Program Administrator maintains file(s) containing your personal information in Canada, generally at 1393 North Service Rd. East, Oakville, Ontario L6H 1A7. You may request access and correct your personal information by contacting the Program Administrator in writing by mail, fax or email. (fax: 1-866-240-4076; email: info@harmonybyorganon.ca; mail: see above).

4. What are your choices?

Participation in the Program is voluntary but to participate, you must agree to the collection, use and disclosure of your personal information as set out in this form.

Withdrawal of consent for participation in Program. If you no longer wish to participate in the Program, you can contact your healthcare provider, health insurer(s) or the Program Administrator by telephone (1-866-556-5663), by mail, fax or email (see above).

Upon receiving your request, you will no longer be enrolled in the Program nor receive assistance with the reimbursement for the product.

I hereby confirm that I wish to enroll in the Program, that I have been given the opportunity to discuss the Program with my healthcare provider (i.e., doctor or nurse) and that I have read the above Program terms and conditions and agree to the collection, use and disclosure of my personal information in accordance with this consent form.

Please fax or email this completed form to 1-866-240-4076 or info@harmonybyorganon.ca

ORGANON

CA-ADA-11059

MEMBER OF INNOVATIVE MEDICINES CANADA

REVIEWED BY PAAB

Pr HADLIMA®
adalimumab injection