Patient Support Program
Harmony By ORGANON

ENROLLMENT FORM

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

HADLIMA®
adalimumab injection

Patient Information

First name | Last name

Sex 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 UNDERSTOOD 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.

Screening/Testing:

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

Please arrange for the following tests:

☐ TB Skin test ☐ TDM Frequency _____
☐ TB QuantiFeron* ☐ Fecal Calprotectin Frequency _____

Provincial formulary code (if applicable):

☐ **Rheumatoid arthritis** (RA) / ☐ **Psoriatic arthritis** (PsA) / ☐ **Ankylosing spondylitis** (AS)
40 mg subcutaneous (sc) every other week

☐ **Crohn's Disease** (CD) / ☐ **Ulcerative Colitis** (UC)
Starting dose (week 0): 160 mg sc, second dose (week 2): 80 mg sc, maintenance dose (week 4+): 40 mg sc every other week

☐ **Hidradenitis Suppurativa** (HS)
Starting dose (week 0): 160 mg sc, second dose (week 2): 80 mg sc, maintenance dose (week 4+): 40 mg sc each week

☐ **Plaque Psoriasis** (PsO) / ☐ **Uveitis** (UV)
Starting dose (week 0): 80 mg sc, maintenance dose (week 1+): 40 mg sc every other week

☐ **Adolescent Hidradenitis Suppurativa** (HS) (12 to 17 years of age weighing ≥30 kg)
Starting dose (week 0): 80 mg sc, subsequent doses (week 1+): 40 mg sc every other week. (40 mg sc every week may be considered if inadequate response)

☐ **Pediatric Polyarticular juvenile idiopathic arthritis** (JIA) (≥2 years of age weighing ≥30 kg)†
Recommended dose: 40 mg sc every other week

☐ **Pediatric Uveitis** (≥2 years of age weighing ≥30 kg)†
Loading dose (week 0): Optional in patients ≥6 years of age weighing ≥30 kg. 80 mg sc
Subsequent doses (week 1+): 40 mg sc every other week

☐ **Other dosing** (specify):

† 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:** 40 mg in 0.8 mL (and/or 0.4 mL when available)
☐ **Pre-filled syringe:** 40 mg in 0.8 mL (and/or 0.4 mL when available)

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

PATIENT'S SIGNATURE OR LEGALLY AUTHORIZED REPRESENTATIVE

SEE FULL PATIENT CONSENT TERMS ON REVERSE. PLEASE ENSURE YOU HAVE READ AND FULLY UNDERSTOOD. **If unable to obtain written consent, document when verbal consent was obtained and by whom. It will allow to initiate the enrollment process.**

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

☐ Verbal consent obtained by:

Name of Health Care Professional | 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 (with any related personal information) 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 de-identified data with Organon Canada Inc. or its affiliated companies ("**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.
- Under certain circumstances and subject to applicable data protection laws, supported by a written request and a proof of identification, you may, for all the personal information that we have collected, used or shared, regarding you, (i) consult it, and/or (ii) ask that it be corrected, and/or (iii) withdraw your consent to our disclosure or use of it. As required or permitted by law, you may also be entitled to: (i) control its dissemination; (ii) receive it computerized in a structured, commonly used and technological format and to have it transferred directly to another organization; (iii) be informed of and submit observations regarding automated decision-making; and (iv) request information about data processing. To exercise any of these rights, please contact us by mailing, emailing or faxing a signed request to the Program Administrator (address: 1-1393 North Service Rd. East, Oakville, ON, 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 judgement.
- 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, disclosure 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 Canada Inc., the sponsor of the Program, and its affiliated companies ("**Organon**") may receive de-identified 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) or aggregated information (personal information combined with the information of other Program participants without the possibility of identifying you) for Program evaluation purposes, such as improving the Program and managing and evaluating enrollment, regulatory purposes, safety and adverse drug event reporting, as well as for other operational and business planning related to the Program or as otherwise permitted or required by applicable laws. Organon may also use de-identified information for future studies or research purposes.

☐ **I do not consent to the use of my de-identified personal information for future studies or research purposes.**

Organon 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, ON, L6H 1A7. You consent to the transfer of your personal information to provinces outside your province of residence (including Quebec), which may have different data protection rules than in your province of residence. While such information is outside of your province of residence, it is subject to the laws of the province in which it is held, and may be subject to disclosure to the governments, courts or law enforcement or regulatory agencies of such other province, pursuant to the laws of such province.

Under certain circumstances and subject to applicable data protection laws, supported by a written request and a proof of identification, you may, for all the personal information that we have collected, used or shared, regarding you, (i) consult it, and/or (ii) ask that it be corrected, and/or (iii) withdraw your consent to our disclosure or use of it. As required or permitted by law, you may also be entitled to: (i) control its dissemination; (ii) receive it computerized in a structured, commonly used and technological format and to have it transferred directly to another organization; (iii) be informed of and submit observations regarding automated decision-making; and (iv) request information about data processing. To exercise any of these rights, please contact us 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