HADLIMA™
(adalimumab-bwwd)
injection, 40 mg/0.4 mL, 40 mg/0.8 mL

Please read the accompanying Medication Guide for HADLIMA, including the information about serious infections and cancers, and discuss it with your doctor. The Instructions for Use and Physician Prescribing Information also are available.

ORGANON Helps

ORGANON PATIENT ASSISTANCE PROGRAM

Please fax or mail the completed, signed, and dated enrollment form to:
FAX: 833-520-1491 • **MAIL:** Organon Patient Assistance Program, PO Box 991624, Louisville, KY 40269
For any questions, please call 888-PAP-0015

PATIENT MUST COMPLETE PAGES 1, 3, 4, AND SIGN IN ALL PLACES WITH A SIGN HERE | **USE A BLACK OR BLUE PEN**

Section 1: Patient and Insurance Information

Patient Information

Patient's First Name: _____ Patient's Last Name: _____

US Resident* ☐ Yes ☐ No **You do not have to be a US citizen to participate.*

Address Line 1: _____

Address Line 2 (Apartment/Unit Number): _____

City: _____ State: _____ Zip: _____

Date of Birth: _____/_____/_____ ☐ I am enrolling for the first time ☐ I am re-enrolling

Provide an email address and a mobile phone number so we may contact you with program notifications and updates

Mobile Phone: _____ Home Phone: _____

Email: _____

I would like my product shipped to: ☐ My Home ☐ My Physician's Office

☐ Other Address: _____

Special delivery instructions: _____

Section 1: Patient and Insurance Information continues on page 3.

WHAT IS HADLIMA?

HADLIMA is a prescription medicine used:

- **To reduce the signs and symptoms of:**
  - **Moderate to severe rheumatoid arthritis (RA) in adults.** HADLIMA can be used alone, with methotrexate, or with certain other medicines.
  - **Moderate to severe polyarticular juvenile idiopathic arthritis (JIA) in children** 2 years of age and older. HADLIMA can be used alone or with methotrexate.
  - **Psoriatic arthritis (PsA) in adults.** HADLIMA can be used alone or with certain other medicines.
  - **Ankylosing spondylitis (AS) in adults.**
  - **Moderate to severe hidradenitis suppurativa (HS) in adults.**
- **To treat moderate to severe Crohn's disease (CD) in adults and children 6 years of age and older.**
- **To treat moderate to severe ulcerative colitis (UC) in adults.** It is not known if adalimumab products are effective in people who stopped responding to or could not tolerate TNF-blocker medicines.
- **To treat moderate to severe chronic (lasting a long time) plaque psoriasis (Ps) in adults** who have the condition in many areas of their body and who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).
- **To treat non-infectious intermediate** (middle part of the eye), **posterior** (back of the eye), and **panuveitis** (all parts of the eye) **in adults.**

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about HADLIMA?

You should discuss the potential benefits and risks of HADLIMA with your doctor. HADLIMA is a tumor necrosis factor (TNF) blocker medicine that can lower the ability of your immune system to fight infections. You should not start taking HADLIMA if you have any kind of infection unless your doctor says it is okay.

Serious infections have happened in people taking adalimumab products. These serious infections include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some people have died from these infections. Your doctor should test you for TB before starting HADLIMA, and check you closely for signs and symptoms of TB during treatment with HADLIMA, even if your TB test was negative. If your doctor feels you are at risk, you may be treated with medicine for TB.

Cancer. For children and adults taking TNF blockers, including HADLIMA, the chance of getting lymphoma or other cancers may increase. There have been cases of unusual cancers in children, teenagers, and young adults using TNF blockers. Some people have developed a rare type of cancer called hepatosplenic T-cell lymphoma. This type of cancer often results in death. If using TNF blockers, including HADLIMA, your chance of getting 2 types of skin cancer (basal cell and squamous cell) may increase. These types are generally not life threatening if treated; tell your doctor if you have a bump or open sore that does not heal.

What should I tell my doctor BEFORE starting HADLIMA?

Tell your doctor about all of your health conditions, including if you:

- Have an infection, are being treated for infection, or have symptoms of an infection.
- Get a lot of infections or infections that keep coming back.
- Have diabetes.
- Have TB or have been in close contact with someone with TB, or were born in, lived in, or traveled where there is more risk for getting TB.
- Live or have lived in an area (such as the Ohio and Mississippi River valleys) where there is an increased risk for getting certain kinds of fungal infections, such as histoplasmosis, coccidioidomycosis, or blastomycosis. These infections may happen or become more severe if you use HADLIMA. Ask your doctor if you are unsure if you have lived in these areas.
- Have or have had hepatitis B.
- Are scheduled for major surgery.
- Have or have had cancer.
- Have numbness or tingling or a nervous system disease, such as multiple sclerosis or Guillain-Barré syndrome.
- Have or had heart failure.
- Have recently received or are scheduled to receive a vaccine. HADLIMA patients may receive vaccines, except for live vaccines. Children should be brought up to date on all vaccines before starting HADLIMA.
- Are allergic to HADLIMA or any of its ingredients.
- Are pregnant, planning to become pregnant, breastfeeding, or planning to breastfeed.
- Have a baby and were using HADLIMA during your pregnancy. Tell your baby's doctor before your baby receives any vaccines.

Also tell your doctor about all the medicines you take. You should not take HADLIMA with ORENCIA® (abatacept), KINERET® (anakinra), REMICADE® (infliximab), ENBREL® (etanercept), CIMZIA® (certolizumab pegol), or SIMPONI® (golimumab). Tell your doctor if you have ever used RITUXAN® (rituximab), IMURAN® (azathioprine), or PURINETHOL® (mercaptopurine, 6-MP).

What should I watch for after starting HADLIMA?

HADLIMA can cause serious side effects, including:

- **Serious infections.** These include TB and infections caused by viruses, fungi, or bacteria. Symptoms related to TB include a cough, low-grade fever, weight loss, or loss of body fat and muscle.
- **Hepatitis B infection in carriers of the virus.** Symptoms include muscle aches, feeling very tired, dark urine, skin or eyes that look yellow, little or no appetite, vomiting, clay-colored bowel movements, fever, chills, stomach discomfort, and skin rash.
- **Allergic reactions.** Symptoms of a serious allergic reaction include hives, trouble breathing, and swelling of your face, eyes, lips, or mouth.
- **Nervous system problems.** Signs and symptoms include numbness or tingling, problems with your vision, weakness in your arms or legs, and dizziness.
- **Blood problems** (decreased blood cells that help fight infections or stop bleeding). Symptoms include a fever that does not go away, bruising or bleeding very easily, or looking very pale.
- **Heart failure** (new or worsening). Symptoms include shortness of breath, swelling of your ankles or feet, and sudden weight gain.
- **Immune reactions including a lupus-like syndrome.** Symptoms include chest discomfort or pain that does not go away, shortness of breath, joint pain, or rash on your cheeks or arms that gets worse in the sun.
- **Liver problems.** Symptoms include feeling very tired, skin or eyes that look yellow, poor appetite or vomiting, and pain on the right side of your stomach (abdomen). These problems can lead to liver failure and death.
- **Psoriasis** (new or worsening). Symptoms include red scaly patches or raised bumps that are filled with pus.

Call your doctor or get medical care right away if you develop any of the above symptoms.

Common side effects of HADLIMA include injection site reactions (pain, redness, rash, swelling, itching, or bruising), upper respiratory infections (sinus infections), headaches, rash, and nausea. These are not all of the possible side effects with HADLIMA. Tell your doctor if you have any side effect that bothers you or that does not go away.

Remember, tell your doctor right away if you have an infection or symptoms of an infection, including:

- Fever, sweats, or chills
- Muscle aches
- Cough
- Shortness of breath
- Blood in phlegm
- Weight loss
- Warm, red, or painful skin or sores on your body
- Diarrhea or stomach pain
- Burning when you urinate
- Urinating more often than normal
- Feeling very tired

HADLIMA is given by injection under the skin.

This is the most important information to know about HADLIMA. For more information, talk to your health care provider.

Please read the accompanying Medication Guide for HADLIMA, including the information about serious infections and cancers, and discuss it with your doctor. The Instructions for Use and Physician Prescribing Information also are available.

HADLIMA™
(adalimumab-bwwd)
injection, 40 mg/0.4 mL, 40 mg/0.8 mL

Patient's First Name: _____ Patient's Last Name: _____

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Section 1 (continued): Patient and Insurance Information

Insurance Information

PLEASE COMPLETE ALL THAT APPLY AND **INCLUDE A FRONT AND BACK COPY OF INSURANCE CARD** FOR EACH TYPE OF INSURANCE

INSURANCE TYPE

☐ No Insurance ☐ Commercial/Private/Employer-Funded: _____

☐ Medicare ☐ Medicaid

PRESCRIPTION INSURANCE

Insurance Company: _____ Insurance Company Phone: _____

Policy ID#: _____ Group #: _____

BIN #: _____ PCN#: _____

MEDICAL INSURER (including Medicaid, Medicare, veterans benefits, and private insurers)

Insurance Company: _____ Insurance Company Phone: _____

Policy ID#: _____ Group #: _____

Policyholder Name: _____ Relationship: _____

Has your employer, insurance company, or another third party directed you to apply to the Organon Patient Assistance Program? ☐ Yes ☐ No

Patients with insurance plans or employers participating in or involved in any way with an alternate funding or similar program (including, but not limited to, patient advocacy programs, specialty networks, SHARx, Paydhealth, or Payer Matrix) requiring or encouraging patients to apply to a manufacturer's patient assistance program or otherwise pursue specialty drug prescription coverage through an alternate funding vendor as a condition of, requirement for, or prerequisite to coverage of relevant Organon products, or that otherwise denies, restricts, eliminates, delays, alters, or withholds any insurance benefits or coverage contingent upon application to, or denial of eligibility for, specialty drug prescription coverage through the alternate funding or similar program are not eligible for the Organon Patient Assistance Program.

Section 2: Income Verification Declarations and Authorization

Provide current monthly household income (your income before taxes), including Social Security and pension benefits

Monthly Household Income: $_____,_____

I understand that the Organon Patient Assistance Program, Inc. (Organon PAP) has the right to verify information about my current gross annual household income in order to ensure that I am qualified for the program and to determine my eligibility to participate in the program.

Number of Household Members (Including Patient) Who Depend on This Income: _____

Section 2: Income Verification Declarations and Authorization continues on page 4.

Patient's First Name: _____ Patient's Last Name: _____

PATIENT MUST COMPLETE PAGES 1, 3, 4, AND SIGN IN ALL PLACES WITH A SIGN HERE | **USE A BLACK OR BLUE PEN**

Section 2 (continued): Income Verification Declarations and Authorization

I certify that all of the information provided in this application, including information about household income, is complete and accurate. I understand that Organon PAP assistance will terminate if the Organon PAP becomes aware of any fraud or if this medication is no longer prescribed for me. I understand that completing this application does not ensure that I will qualify for patient assistance. I certify that I will not seek reimbursement or credit for this prescription from any insurer, health plan, or government program. If I am a member of a Medicare Part D plan, I will not seek to have the prescription or any cost associated with it counted as part of my out-of-pocket cost for prescription drugs. I understand that Organon PAP reserves the right to modify the application form, modify or discontinue this program, or terminate assistance at any time and without notice. I authorize Organon PAP and its affiliates to forward the prescription to a dispensing pharmacy on my behalf. Organon PAP is not acting as a dispensing pharmacy. Organon PAP is not responsible for verifying any information contained in the prescription forwarded as part of the enrollment process, including, without limitation, allergies, medical conditions, or other medications being taken by me. I understand that I will notify the Organon PAP immediately if anything changes with my prescription, income, or my insurance coverage. I understand that the Organon PAP reserves the right to request documentation to verify the information provided in this application for purposes of determining my eligibility for assistance and to conduct periodic audits of my enrollment, including the health care provider who will be supervising my treatment, to verify the information provided herein. I understand that assistance received through the Organon PAP is not insurance.

SIGN HERE **Patient's Original Signature** _____ **Date** M M D D Y Y Y Y

Section 3: Patient Authorization

I authorize my health care provider(s), pharmacies, and my health plan(s), including Medicare, to disclose to the Organon Patient Assistance Program and other contracted third parties involved in administering the Organon Patient Assistance Program (collectively, the "PAP") my personal health information, including the information provided by my health care provider on the PAP application form and other information related to my participation in the PAP (collectively, "My Information"), so that the PAP may use the information to (i) assess my qualification for the PAP, (ii) provide me with PAP assistance, (iii) administer the PAP, (iv) monitor, audit, access and evaluate the PAP's implementation and effectiveness, and (v) contact me via mail, email, text message, phone or fax for PAP-related purposes, including as part of PAP audits and to request additional information from me. I authorize the PAP to use My Information for the foregoing purposes, as well as to disclose My Information to auditors of the PAP and to my health plan(s), including Medicare, so that I may receive assistance from the PAP if I am eligible. I understand that My Information, once disclosed pursuant to this authorization, may no longer be protected by federal law and could be re-disclosed to others, but I also understand that the PAP intends to use and disclose My Information only for the purposes stated herein. I understand that I do not need to sign this authorization in order to receive health care treatment or insurance benefits, but that if I do not sign the authorization, I will not be able to obtain assistance from the PAP. I further understand that I may cancel the authorization at any time by telephoning the Organon Patient Assistance Program at 1-888-PAP-0015 or sending a written notice of cancellation by mail to Organon Patient Assistance Program, P.O. Box 991624, Louisville, KY 40269.

I understand that if I cancel the authorization, that will not invalidate uses and disclosures of My Information made in reliance on the authorization before the PAP received notice of my cancellation. If I do not cancel this authorization, the authorization will remain in effect for 15 months from the date of my signature below (or the maximum period allowed by applicable state or local law, if less than 15 months). I have read this document or have had it explained to me.

I understand that I may request a copy of this authorization once it has been signed.

By signing below, I certify that I have reviewed, read, understand, and agree to this authorization and that all information is correct, complete, and accurate.

SIGN HERE **Patient's Original Signature** _____ **Date** M M D D Y Y Y Y

This form should not be tampered with or revised in any way.

To report an adverse event to a specific Organon product, including death due to any cause, please contact the Organon National Service Center at 844-674-3200.

PHYSICIAN/PRESCRIBER MUST COMPLETE THIS PAGE AND SIGN IN ALL PLACES WITH A SIGN HERE | USE A BLACK OR BLUE PEN

Section 4: Prescription Information

THIS IS THE PRESCRIPTION. PLEASE DO NOT SUBMIT A PRESCRIPTION SEPARATE FROM THIS APPLICATION.

Patient's First Name: _____ Patient's Last Name: _____

Date of Birth:_____/_____/_____ Weight:_____

Allergies: ☐ No Known ☐ Other: _____

Medical Conditions: ☐ No Known ☐ Other: _____

Current Medications: _____

HADLIMA™ (adalimumab-bwwd) THERAPY OPTIONS:

Prefilled Autoinjector Pen (HADLIMA™ PushTouch™)

☐ HADLIMA 40 mg/0.4 mL (high concentration, citrate-free)

☐ HADLIMA 40 mg/0.8 mL (low concentration, citrate-containing)

Prefilled Syringe

☐ HADLIMA 40 mg/0.4 mL (high concentration, citrate-free)

☐ HADLIMA 40 mg/0.8 mL (low concentration, citrate-containing)

Directions for Use _____

QUANTITY: ☐ 84-Day Supply (Program Standard) ☐ Other: _____ **REFILLS:** ☐ 1 year ☐ Other: _____

☐ Dispense as written

SIGN HERE **Physician/Prescriber's Original Signature** _____ **Date** M M D D Y Y Y Y

Section 5: Physician/Prescriber Information

Prescriber's First Name: _____ M.I.: _____

Prescriber's Last Name: _____ Professional Designation: _____

Physician/Prescriber NPI Number: _____

Name of Facility/Site: _____

Mailing Address (PO Boxes not permitted): _____ Suite/Bldg/Floor: _____

City: _____ State: _____ Zip: _____

Office Phone: _____ Ext: _____ Secure Fax: _____

Office Contact Name_____ Email Address _____

Physician/Prescriber Attestation

I certify that this prescription is medically appropriate for this patient and that I will be supervising the patient's treatments. I verify that the information provided is complete and accurate to the best of my knowledge. I authorize the Organon Patient Assistance Program (Organon PAP), its affiliated companies, or its subcontractors to forward this prescription to a dispensing pharmacy on behalf of me and my patient. I understand that Organon PAP reserves the right to modify or discontinue this program at this facility/practice or terminate assistance at any time and without notice. I certify that I will not seek reimbursement or credit for this prescription from any insurer, health plan, or government program. I understand that Organon PAP reserves the right to conduct periodic audits and to request documentation to verify the information provided in this application as it relates to Organon PAP for purposes of determining eligibility of the patient.

SIGN HERE **Physician/Prescriber's Original Signature** _____ **Date** M M D D Y Y Y Y