

MEDICATION GUIDE
HADLIMA™ (HAD-lee-mah)
(adalimumab-bwwd)
injection, for subcutaneous use

Read the Medication Guide that comes with HADLIMA before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment.

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

HADLIMA is a medicine that affects your immune system. HADLIMA can lower the ability of your immune system to fight infections. **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.
- Your doctor should check you closely for signs and symptoms of TB during treatment with HADLIMA.

You should not start taking HADLIMA if you have any kind of infection unless your doctor says it is okay.

Before starting HADLIMA, tell your doctor if you:

- think you have an infection or have symptoms of an infection such as:
 - fever, sweats, or chills
 - muscle aches
 - cough
 - shortness of breath
 - blood in phlegm
 - warm, red, or painful skin or sores on your body
 - diarrhea or stomach pain
 - burning when you urinate or urinate more often than normal
 - feel very tired
 - weight loss
- are being treated for an infection.
- get a lot of infections or have infections that keep coming back.
- have diabetes.
- have TB, or have been in close contact with someone with TB.
- were born in, lived in, or traveled to countries where there is more risk for getting TB. Ask your doctor if you are not sure.
- live or have lived in certain parts of the country (such as the Ohio and Mississippi River valleys) where there is an increased risk for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, or blastomycosis). These infections may happen or become more severe if you use HADLIMA. Ask your doctor if you do not know if you have lived in an area where these infections are common.
- have or have had hepatitis B.
- use the medicine ORENCIA (abatacept), KINERET (anakinra), RITUXAN (rituximab), IMURAN (azathioprine), or PURINETHOL (6-mercaptopurine, 6-MP).
- are scheduled to have major surgery

After starting HADLIMA, call your doctor right away if you have an infection, or any sign of an infection.

HADLIMA can make you more likely to get infections or make any infection that you may have worse.

Cancer

- For children and adults taking Tumor Necrosis Factor (TNF)-blockers, including HADLIMA, the chances of getting cancer may increase.
- There have been cases of unusual cancers in children, teenagers, and young adults using TNF-blockers.

- People with rheumatoid arthritis (RA), especially more serious RA, may have a higher chance for getting a kind of cancer called lymphoma.
- If you use TNF blockers including HADLIMA, your chance of getting two types of skin cancer may increase (basal cell cancer and squamous cell cancer of the skin). These types of cancer are generally not life-threatening if treated. Tell your doctor if you have a bump or open sore that does not heal.
- Some people receiving TNF blockers including HADLIMA developed a rare type of cancer called hepatosplenic T-cell lymphoma. This type of cancer often results in death. Most of these people were male teenagers or young men. Also, most people were being treated for Crohn's disease or ulcerative colitis with another medicine called IMURAN® (azathioprine) or PURINETHOL® (6-mercaptopurine, 6-MP).

What is HADLIMA?

HADLIMA is a medicine called a Tumor Necrosis Factor (TNF) blocker. HADLIMA is 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 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.**
- **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).

What should I tell my doctor before taking HADLIMA?

HADLIMA may not be right for you. Before starting HADLIMA, tell your doctor about all of your medical conditions, including if you:

- have an infection. See **"What is the most important information I should know about HADLIMA?"**
- have or have had cancer.
- have any numbness or tingling or have a disease that affects your nervous system such as multiple sclerosis or Guillain-Barré syndrome.
- have or had heart failure.
- have recently received or are scheduled to receive a vaccine. You may receive vaccines, except for live vaccines while using HADLIMA. Children should be brought up to date with all vaccines before starting HADLIMA.
- are allergic to HADLIMA or to any of its ingredients. See the end of this Medication Guide for a list of ingredients in HADLIMA.
- are pregnant or plan to become pregnant, breastfeeding or plan to breastfeed. You and your doctor should decide if you should take HADLIMA while you are pregnant or breastfeeding.
- have a baby and you were using HADLIMA during your pregnancy. Tell your baby's doctor before your baby receives any vaccines.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your doctor if you use:

- ORENCIA (abatacept), KINERET (anakinra), REMICADE (infliximab), ENBREL (etanercept), CIMZIA (certolizumab pegol) or SIMPONI (golimumab), because you should not use HADLIMA while you are also using one of these medicines.
- RITUXAN (rituximab). Your doctor may not want to give you HADLIMA if you have received RITUXAN (rituximab) recently.
- IMURAN (azathioprine) or PURINETHOL (6–mercaptopurine, 6-MP).

Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

How should I take HADLIMA?

- HADLIMA is given by an injection under the skin. Your doctor will tell you how often to take an injection of HADLIMA. This is based on your condition to be treated. **Do not inject HADLIMA more often than you were prescribed.**
- See the **Instructions for Use** inside the carton for complete instructions for the right way to prepare and inject HADLIMA.
- Make sure you have been shown how to inject HADLIMA before you do it yourself. You can call your doctor or 1-844-674-3200 if you have any questions about giving yourself an injection. Someone you know can also help you with your injection after they have been shown how to prepare and inject HADLIMA.
- **Do not** try to inject HADLIMA yourself until you have been shown the right way to give the injections. If your doctor decides that you or a caregiver may be able to give your injections of HADLIMA at home, you should receive training on the right way to prepare and inject HADLIMA.
- Do not miss any doses of HADLIMA unless your doctor says it is okay. If you forget to take HADLIMA, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. This will put you back on schedule. In case you are not sure when to inject HADLIMA, call your doctor or pharmacist.
- If you take more HADLIMA than you were told to take, call your doctor.

What are the possible side effects of HADLIMA?

HADLIMA can cause serious side effects, including:

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

- **Serious Infections.**
Your doctor will examine you for TB and perform a test to see if you have TB. If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with HADLIMA and during treatment with HADLIMA. Even if your TB test is negative your doctor should carefully monitor you for TB infections while you are taking HADLIMA. People who had a negative TB skin test before receiving adalimumab products have developed active TB. Tell your doctor if you have any of the following symptoms while taking or after taking HADLIMA:
 - cough that does not go away
 - weight loss
 - low grade fever
 - loss of body fat and muscle (wasting)
- **Hepatitis B infection in people who carry the virus in their blood.**
If you are a carrier of the hepatitis B virus (a virus that affects the liver), the virus can become active while you use HADLIMA. Your doctor should do blood tests before you start treatment, while you are using HADLIMA, and for several months after you stop treatment with HADLIMA. Tell your doctor if you have any of the following symptoms of a possible hepatitis B infection:
 - muscle aches
 - feel very tired
 - dark urine
 - skin or eyes look yellow
 - little or no appetite
 - vomiting
 - clay-colored bowel movements
 - fever
 - chills
 - stomach discomfort
 - skin rash

- **Allergic reactions.** Allergic reactions can happen in people who use HADLIMA. Call your doctor or get medical help right away if you have any of these symptoms of a serious allergic reaction:
 - hives
 - swelling of your face, eyes, lips or mouth
 - trouble breathing
- **Nervous system problems.** Signs and symptoms of a nervous system problem include: numbness or tingling, problems with your vision, weakness in your arms or legs, and dizziness.
- **Blood problems.** Your body may not make enough of the blood cells that help fight infections or help to stop bleeding. Symptoms include a fever that does not go away, bruising or bleeding very easily, or looking very pale.
- **New heart failure or worsening of heart failure you already have. Call your doctor right away** if you get new worsening symptoms of heart failure while taking HADLIMA, including:
 - shortness of breath
 - swelling of your ankles or feet
 - 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 a rash on your cheeks or arms that gets worse in the sun. Symptoms may improve when you stop HADLIMA.
- **Liver problems.** Liver problems can happen in people who use TNF-blocker medicines. These problems can lead to liver failure and death. Call your doctor right away if you have any of these symptoms:
 - feel very tired
 - skin or eyes look yellow
 - poor appetite or vomiting
 - pain on the right side of your stomach (abdomen)
- **Psoriasis.** Some people using adalimumab products had new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red scaly patches or raised bumps that are filled with pus. Your doctor may decide to stop your treatment with HADLIMA.

Call your doctor or get medical care right away if you develop any of the above symptoms. Your treatment with HADLIMA may be stopped.

The most common side effects of HADLIMA include:

- injection site reactions: redness, rash, swelling, itching, or bruising. These symptoms usually will go away within a few days. Call your doctor right away if you have pain, redness or swelling around the injection site that does not go away within a few days or gets worse.
- upper respiratory infections (including sinus infections)
- headaches
- rash

These are not all the possible side effects with HADLIMA. Tell your doctor if you have any side effect that bothers you or that does not go away. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

How should I store HADLIMA?

- Store HADLIMA in the refrigerator at 36°F to 46°F (2°C to 8°C). Store HADLIMA in the original carton until use to protect it from light.
- **Do not freeze HADLIMA.** Do not use HADLIMA if frozen, even if it has been thawed.
- Refrigerated HADLIMA may be used until the expiration date printed on the HADLIMA carton, dose pack, autoinjector or prefilled syringe. Do not use HADLIMA after the expiration date.

- If needed, for example when you are traveling, you may also store HADLIMA PushTouch or prefilled syringe at room temperature up to 77°F (25°C) for up to 14 days. Store HADLIMA PushTouch or prefilled syringe in the original carton until use to protect it from light.
- Throw away HADLIMA PushTouch or prefilled syringe if it has been kept at room temperature and not been used within 14 days.
- Record the date you first remove HADLIMA PushTouch or prefilled syringe from the refrigerator in the spaces provided on the carton and dose pack.
- Do not store HADLIMA in extreme heat or cold.
- The solution should be clear and colorless to pale brown. Do not use an autoinjector or prefilled syringe if the liquid is cloudy, discolored, or has flakes or particles in it.
- Do not drop or crush HADLIMA. The prefilled syringe is glass.

Keep HADLIMA, injection supplies, and all other medicines out of the reach of children.

General information about the safe and effective use of HADLIMA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use HADLIMA for a condition for which it was not prescribed. Do not give HADLIMA to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about HADLIMA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about HADLIMA that is written for health professionals. For more information go to www.HADLIMA.com or call Organon LLC, a subsidiary of Organon & Co., at 1-844-674-3200.

What are the ingredients in HADLIMA?

Active ingredient: adalimumab-bwwd

HADLIMA PushTouch 40 mg/0.8 mL, HADLIMA 40 mg/0.8 mL prefilled syringe, and HADLIMA 40 mg/0.8 mL institutional use vial:

Inactive ingredients: citric acid monohydrate, L-histidine, L-histidine hydrochloride monohydrate, polysorbate 20, sodium citrate dihydrate, sorbitol, and Water for Injection, USP.


HADLIMA PushTouch 40 mg/0.4 mL and HADLIMA 40 mg/0.4 mL prefilled syringe:

Inactive ingredients: L-histidine, L-histidine hydrochloride monohydrate, mannitol, polysorbate 20, sodium phosphate dibasic heptahydrate, sodium phosphate monobasic monohydrate, sodium succinate dibasic, succinic acid, and Water for Injection, USP

SAMSUNG BIOEPIS

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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