

Hello

Meet

Hulio[®]

(adalimumab-fkjp) injection



IMPORTANT SAFETY INFORMATION

What is the most important information I should know about HULIO[®] (adalimumab-fkjp)?

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

Serious 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 HULIO and check you closely for signs and symptoms of TB during treatment with HULIO, even if your TB test was negative. If your doctor feels you are at risk, you may be treated with medicine for TB.

Please see additional Important Safety Information and Indications on pages 18-19, and accompanying Full Prescribing Information and Medication Guide.



Let's get going

Yes, having a chronic condition might feel like a lot. The good news is that Hulio[®] may help treat your condition, and we'll make sure you have the support and information you need to get started and keep going with treatment.

IMPORTANT SAFETY INFORMATION (continued)

Cancer

- For children and adults taking TNF blockers, including HULIO, 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 HULIO, your chance of getting two 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 doesn't heal.

 **Hulio[®]**
(adalimumab-fkjp) injection

You're starting a biosimilar

Specifically, a biosimilar to Humira® (adalimumab) called HULIO (adalimumab-fkjp) injection. That means HULIO works like Humira. Provides relief like Humira. And is as safe as Humira.^{1,2}

Okay

what's a biosimilar?

A biosimilar is a biologic drug that's highly similar to the original approved medicine. Since it's a near-exact copy of the original, there are no clinically meaningful differences between the two drugs.²

TOP 3 POTENTIAL BENEFITS OF BIOSIMILARS

1

Undergoes careful
FDA review to
ensure confidence²

2

Delivers similar
safety and
effectiveness²

3

Helps improve
access to biologic
medicines³

IMPORTANT SAFETY INFORMATION (continued)

What should I tell my doctor BEFORE starting HULIO?

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

Please see additional Important Safety Information and Indications on pages 18-19, and accompanying [Full Prescribing Information](#) and [Medication Guide](#).

IMPORTANT SAFETY INFORMATION (continued)

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

- 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 HULIO. Ask your doctor if you are unsure if you have lived in these areas
- Have or have had hepatitis B

 **Hulio**[®]
(adalimumab-fkjp) injection



HULIO is approved for the following inflammatory diseases

This is the recommended dosing schedule. Your doctor may adjust depending on your condition and needs.

Moderate to Severe
Hidradenitis Suppurativa
in Adults

RECOMMENDED DOSING

Day 01: **160 mg***
Day 15: **80 mg**
Day 29: **40 mg every week**
or 80 mg every other week

*Taken in 1 day or split over 2 consecutive days.

Moderate to Severe Chronic
Plaque Psoriasis
in Adults

RECOMMENDED DOSING

Day 01: **80 mg**
Day 08: **40 mg every other week**

Non-infectious
Uveitis
in Adults

RECOMMENDED DOSING

Day 01: **80 mg**
Day 08: **40 mg every other week**

Moderate to Severe
Crohn's Disease
in Adults and Children
6 Years and Older

RECOMMENDED DOSING

Day 01: **160 mg***
Day 15: **80 mg**
Day 29: **40 mg every other week**
for children ≥88 lbs and adults

Day 01: **80 mg**
Day 15: **40 mg**
Day 29: **20 mg every other week**
for children 37 lbs to <88 lbs

*Taken in 1 day or split over 2 consecutive days.

Moderate to Severe
Ulcerative Colitis
in Adults

RECOMMENDED DOSING

Day 01: **160 mg***
Day 15: **80 mg**
Day 29: **40 mg every other week**

*Taken in 1 day or split over 2 consecutive days.

Moderate to Severe
Rheumatoid Arthritis
in Adults

Active
Ankylosing Spondylitis
in Adults

Active
Psoriatic Arthritis
in Adults

RECOMMENDED DOSING
FOR ALL OF THE ABOVE

40 mg every other week

Moderate to Severe Polyarticular
Juvenile Idiopathic Arthritis
in Children 2 Years and Older

RECOMMENDED DOSING

20 mg every other week
for children 33 lbs to <66 lbs
40 mg every other week
for children ≥66 lbs

Helps treat the inflammation associated with your condition

HULIO works by blocking a certain protein in the body called TNF-α. Having too much TNF-α causes inflammation that can increase disease symptoms. By blocking TNF-α, adalimumab is proven effective at reducing inflammation.¹

IMPORTANT SAFETY INFORMATION (continued)

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

- 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. HULIO patients may receive vaccines, except for live vaccines. Children should be brought up to date on all vaccines before starting HULIO

Please see additional Important Safety Information and Indications on pages 18-19, and accompanying Full Prescribing Information and Medication Guide.

IMPORTANT SAFETY INFORMATION (continued)

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

- Are allergic to HULIO or to any of its ingredients
- Are pregnant, planning to become pregnant, breastfeeding, or planning to breastfeed
- Have a baby and you were using HULIO during your pregnancy. Tell your baby's doctor before your baby receives any vaccines



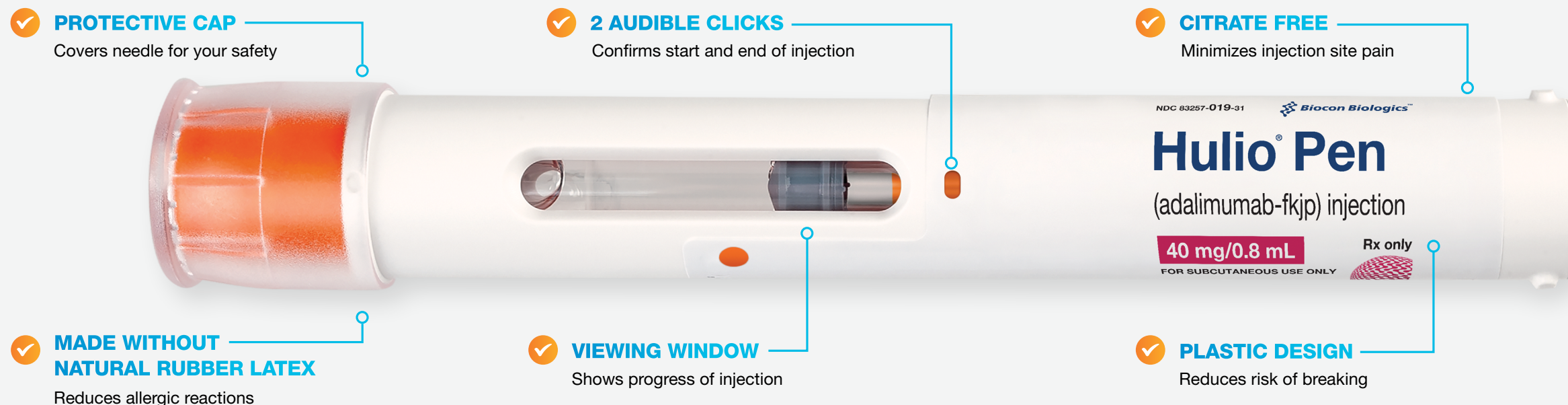
Click, Click, Go

HULIO is built with you in mind

There's no button to press. Just push the device against the skin to start the injection and watch the indicator display your progress.



HULIO is also available as a
Prefilled Syringe



SEE HOW TO USE HULIO

Scan here to watch a video on how to prepare and use your prefilled pen or syringe.



Be sure to read the full Instructions for Use and ask your healthcare provider if you have any questions.



Your prefilled pen or syringe may or may not include the HULIO logo.

IMPORTANT SAFETY INFORMATION (continued)

Also tell your doctor about all the medicines you take. You should not take HULIO 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® (6-mercaptopurine, 6-MP).

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IMPORTANT SAFETY INFORMATION (continued)

What should I watch for AFTER starting HULIO?

HULIO 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.

 **Hulio**
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Hulio360™

Designed Around You



With a range of comprehensive resources, our HULIO360 support program is designed to make your treatment experience as easy as possible.

1. SETTING UP YOUR TREATMENT



Enrollment Support

Get assistance with enrolling in our support services.



Coverage Support

A Patient Onboarding Specialist can help you understand your insurance coverage and provide information on alternative options, if needed, for gaining access to your medication.



Copay Assistance*

We can determine eligibility for copay assistance to lower out-of-pocket costs if you're commercially insured with product coverage.

2. STARTING YOUR TREATMENT



Welcome Kit & Travel Bag

You'll receive a welcome kit with information about your medication and an insulated bag to take it wherever you go.



Injection Training†

An In-home Injection Training Nurse can teach you proper injection technique, or a Pharmacist Educator can provide training support virtually.



Sharps Program

HULIO360 can provide you with a sharps disposal container and guidance for disposing used injection devices upon request.

3. STAYING ON TREATMENT



Injection Reminders†

Opt in to receive text reminders when it is time for your medication.



Pharmacist Support†

Get ongoing clinical support from a Pharmacist Educator to address any potential concerns while taking HULIO.



Scan the QR code to watch a complete overview of the support you can receive once enrolled with HULIO360.

IMPORTANT SAFETY INFORMATION (continued)

HULIO can cause serious side effects, including: (continued)

- **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.

Please see additional Important Safety Information and Indications on pages 18-19, and accompanying [Full Prescribing Information](#) and [Medication Guide](#).

*Eligibility restrictions apply. Not valid for uninsured patients or patients who are covered by a state- or federal-funded healthcare program. See [hulio.com/Hulio360](#) for details and full terms and conditions.

†Available for patients who opt in to this service.

 **Hulio®**
(adalimumab-fkjp) injection

We've got your back

Hulio360[®]

Designed Around You

Hulio[®]

(adalimumab-fkjp) injection

Pay as little as \$0 per month*

For HULIO[®] (adalimumab-fkjp) injection or adalimumab-fkjp injection

RxBIN: XXXXXX RxPCN: XXXX RxGrp: XXXXXXXX RxID: XXXXXXXXXXXX

*Eligibility restrictions apply. For full terms and conditions, visit, www.hulio.com/copay.

When you enroll in HULIO360, we'll work with you to see if you are eligible for copay assistance to pay as little as \$0 a month.*



A Patient Onboarding Specialist can help you enroll in HULIO360 or provide program information. Call us at **1-833-44-HULIO (1-833-444-8546)** Monday through Friday, 8 AM to 8 PM ET.

*Eligible commercially insured patients may pay as little as \$0 for each monthly fill of HULIO[®] (adalimumab-fkjp) injection or adalimumab-fkjp injection while this program remains in effect. See hulio.com/Hulio360 for details and full terms and conditions.

IMPORTANT SAFETY INFORMATION (continued)

HULIO can cause serious side effects, including: (continued)

- **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.

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IMPORTANT SAFETY INFORMATION (continued)

HULIO can cause serious side effects, including: (continued)

- **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.





Biosimilars aren't just what we do— they're *all* we do.

Each year, biosimilars save the US healthcare system over \$5 billion.^{4*}

By increasing the availability of high-quality biosimilars such as HULIO (adalimumab-fkjp) injection here and around the world, Biocon Biologics aims to help make a meaningful difference for you.

*Estimated decrease in direct spending on biologic drugs from 2014 through 2024.

- > **5.5 MILLION PATIENTS**
treated in over 100 countries
- > **8 BIOSIMILARS**
available worldwide
- > **20+ BIOSIMILARS**
approved or in development



Important information to know about HULIO

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Cancer

- For children and adults taking TNF blockers, including HULIO, 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 HULIO, your chance of getting two 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 doesn't heal.

What should I tell my doctor BEFORE starting HULIO?

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 HULIO. Ask your doctor if you are unsure if you have lived in an area where these infections are common
- 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. HULIO patients may receive vaccines, except for live vaccines. Children should be brought up to date on all vaccines before starting HULIO
- Are allergic to HULIO or to any of its ingredients
- Are pregnant, planning to become pregnant, breastfeeding, or planning to breastfeed
- Have a baby and you were using HULIO 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 HULIO 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 HULIO?

HULIO 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.

The most common side effects of HULIO include injection site reactions (pain, redness, rash, swelling, itching, or bruising), **upper respiratory infections** (sinus infections), **headaches**, and **rash**. These are not all of the possible side effects with HULIO. 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

If you have any questions about this information, be sure to discuss them with your healthcare provider. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088. Please see [Prescribing Information](#) and [Medication Guide](#).

APPROVED USES

HULIO is a prescription medicine used:

- **To reduce the signs and symptoms of:**
 - **Moderate to severe rheumatoid arthritis (RA) in adults.** HULIO can be used alone, with methotrexate, or with certain other medicines. HULIO may prevent further damage to your bones and joints and may help your ability to perform daily activities.
 - **Moderate to severe polyarticular juvenile idiopathic arthritis (JIA) in children 2 years of age and older.** HULIO can be used alone or with methotrexate.
 - **Psoriatic arthritis (PsA) in adults.** HULIO can be used alone or with certain other medicines. HULIO may prevent further damage to your bones and joints and may help your ability to perform daily activities.
 - **Ankylosing spondylitis (AS) in adults.**
 - **Moderate to severe hidradenitis suppurativa 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 plaque psoriasis (Ps) in adults** who are ready for systemic therapy or phototherapy and are under the care of a doctor who will decide if other systemic therapies are less appropriate.
- **To treat non-infectious intermediate** (middle part of the eye), **posterior** (back of the eye), **and panuveitis** (all parts of the eye) **in adults.**

Please see accompanying [Full Prescribing Information](#) and [Medication Guide](#).

References: **1.** HULIO. Product information. Biocon Biologics Inc. 2023. **2.** US Food and Drug Administration. Biosimilar basics for patients. 2023. Accessed April 04, 2024. <https://www.fda.gov/drugs/biosimilars/biosimilar-basics-patients> **3.** Dranitsaris G, Jacobs I, Kirchhoff C, Popovian R, Shane LG. Drug tendering: drug supply and shortage implications for the uptake of biosimilars. *Clinicoecon Outcomes Res.* 2017;9:573-584. **4.** Mulcahy AW, Hlavka JP, Case SR. Biosimilar cost savings in the United States: initial experience and future potential. *Rand Health Q.* 2018;7(4):3.

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You got this