

IMPORTANT SAFETY INFORMATION:

WARNING: SERIOUS INFECTIONS AND MALIGNANCY SERIOUS INFECTIONS

Patients treated with adalimumab products, including HYRIMOZ®, are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue HYRIMOZ if a patient develops a serious infection or sepsis. Reported infections include:

 Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before HYRIMOZ use and during therapy. Initiate treatment for latent TB prior to HYRIMOZ use

Why choose HYRIMOZ® (adalimumab-<mark>adaz</mark>)?

patient-days of experience³

Commercial patients have preferred access with the largest PBMsb, including Express Scripts®, Optum Rx®, CVS Caremark®, and UnitedHealthcare®4

Financial support options are available for eligible patients, including a co-pay as low as \$0° and a one-time reimbursement to help offset the cost of switching from Humira®.d

Based on an analysis of volume of worldwide sales (in KG) for the period of March to August 2022. Not all products were available in all countries surveyed. Analysis included Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, Switzerland, UK, Ukraine, Algeria, Argentina, Australia, Brazil, Central America, Canada, Chile, China, Colombia, Egypt, Fr. W. Africa, Japan, Jordan, Kazakhstan, Korea, Kuwait, Lebanon, Mexico, Morocco, New Zealand, Peru, Saudi Arabia, South Africa, Taiwan, Turkey, UAE, and US. Custom client formularies may differ.

See full terms and conditions at <u>HYRIMOZ.com/pro/patient-support</u>.

Eligible patients may receive a one-time reimbursement of up to \$200 for out-of-pocket costs associated with transitioning to HYRIMOZ to be used for healthcare-related expenses. For patients with commercial insurance only. Must present proof of HYRIMOZ prescription for an approved indication within previous 90 days. Not available in IL, MA, MI, MN, MS, RI, or where prohibited by law. Additional terms and conditions at portal.trialcard.com/sandoz/hyrimoz. PBM=pharmacy benefit manager.

IMPORTANT SAFETY INFORMATION (cont'd):

WARNING: SERIOUS INFECTIONS AND MALIGNANCY (cont'd) SERIOUS INFECTIONS (cont'd)

- Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness
- · Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria

Carefully consider the risks and benefits of treatment with HYRIMOZ prior to initiating therapy in patients with chronic or recurrent infection.

Monitor patients closely for the development of signs and symptoms of infection during and after treatment with HYRIMOZ, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

40 mg/0.4 mL for injection

HYRIMOZ[®] offers what you have come to expect from Humira[®] (adalimumab)

	HYRIMOZ	Humira®
Approved safety and efficacy profile for patients with immunological conditions ^{5,6}	✓	✓
High-concentration, citrate-free formulation	/	/
10 dosing options available ⁷	/	/
Autoinjector pen	/	/
Comprehensive patient support offerings	/	/
Real-world evidence ⁸⁻¹⁰	/	/



Both HYRIMOZ and adalimumab-adaz offer these benefits for your patients who are starting or switching to a Sandoz product.

IMPORTANT SAFETY INFORMATION (cont'd):

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including adalimumab products. Post-marketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF-blockers including adalimumab products. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. Almost all these patients had received treatment with azathioprine or 6-mercaptopurine (6-MP) concomitantly with a TNF blocker at or prior to diagnosis. It is uncertain whether the occurrence of HSTCL is related to use of a TNF blocker or a TNF blocker in combination with these other immunosuppressants.



HYRIMOZ® and adalimumab-adaz are the same medicine

Offering **2 presentations** ensures broader access for your patients. Insurance coverage will determine whether your patient receives HYRIMOZ or adalimumab-adaz.





HYRIMOZ

(High WAC)

adalimumab-adaz

(Low WAC)



High-concentration, citrate-free formulation





Sensoready® pen autoinjectora





Co-pay card with \$0 co-pay for eligible patients^b





Access to support from Sandoz One Source





One-time reimbursement for eligible switch patients





Look for the suffix "adaz" in the EHR

Ensure your patients are receiving the adalimumab biosimilar by Sandoz.

EHR=electronic health record; WAC=wholesale acquisition cost.

IMPORTANT SAFETY INFORMATION (cont'd): WARNINGS AND PRECAUTIONS

Serious Infections

- Do not start HYRIMOZ during an active infection, including localized infections
- If an infection develops, monitor carefully, and stop HYRIMOZ if infection becomes serious. Drug interactions with biologic products: A higher rate of serious infections has been observed in RA patients treated with rituximab who received subsequent treatment with a TNF blocker. An increased risk of serious infections has been seen with the combination of TNF blockers with anakinra or abatacept, with no demonstrated added benefit in patients with RA. Concomitant administration of HYRIMOZ with other biologic DMARDs (eg, anakinra or abatacept) or other TNF blockers is not recommended based on the possible increased risk for infections and other potential pharmacological interactions



^aAlso available in a prefilled syringe for certain dosages.

bTerms and Conditions apply.

HYRIMOZ® and adalimumab-adaz presentations and packaging

Packs and Presentations	Available Strengths High-concentration formulation Citrate-free	HYRIMOZ and adalimumab-adaz	Other adalimumab biosimilars ^a	
Autoinjector Starter Packs				
CD, UC, or HS	80 mg/0.8 mL	✓		
Ps or UV	80 mg/0.8 mL and 40 mg/0.4 mL	✓		
Prefilled Syringe Starter Packs				
	80 mg/0.8 mL	✓		
Pediatric CD	80 mg/0.8 mL and 40 mg/0.4 mL	✓		
Autoinjector Maint	enance Doses			
80 mg/0.8 mL		✓		
40 mg/0.4 mL		//	/	
Prefilled Syringe Maintenance Doses				
80 mg/0.8 mL		✓		
40 mg/0.4 mL		/ /	/	
20 mg/0.2 mL		✓		
10 mg/0.1 mL		✓		

HYRIMOZ is the only adalimumab biosimilar that offers all the same dosing options as Humira[®], including starter packs.^{7a}

"Based on commercial availability of the following products as of July 2023: Amjevita™, Cyltezo®, Hadlima™, Hulio®, Yusimry™, Idacio®, and Yuflyma®. CD=Crohn's disease; HS=hidradenitis suppurativa; Ps=plaque psoriasis; UC=ulcerative colitis; UV=uveitis.

IMPORTANT SAFETY INFORMATION (cont'd): WARNINGS AND PRECAUTIONS (cont'd) Serious Infections (cont'd)

- Patients 65 years of age and older, patients with co-morbid conditions and/or patients taking concomitant immunosuppressants may be at greater risk of infection
- Invasive fungal infections: For patients who develop a systemic illness on HYRIMOZ, consider empiric antifungal therapy for those who reside or travel to regions where mycoses are endemic

Malignancies

• In clinical trials, incidence of malignancies was greater in adalimumab-treated patients than in controls



Sandoz One Source for HYRIMOZ® and adalimumab-adaz can help ensure a seamless start or switch

Co-pay as low as \$0 for eligible commercially insured patients

Terms and conditions apply. Visit <u>HYRIMOZ.com/pro/patient-support</u> for full terms.





Available to patients prescribed HYRIMOZ and adalimumab-adaz



Patients can enroll themselves online, via text, or over the phone



Instant access means cards are available immediately for those who qualify



No expiration, with automatic annual reset of card benefits

Other support services available through

one source

- HYRIMOZ Field Reimbursement Managers
- Benefits investigation and prior authorization support
 PA requests initiated through CoverMyMeds®
- · QuickStart program
- · Sensoready® pen demonstration kits

- Nurse ambassadors
- Injection training
- Refill reminders
- Sharps containers



To learn more about any of these services, visit HYRIMOZ.com/pro/patient-support.

PA=prior authorization.





A ONE-TIME \$200

REIMBURSEMENT

For eligible patients who switch from Humira® to HYRIMOZ® or adalimumab-adaz®

READY TO MAKE THE SWITCH?

- Patients can text "HYRIMOZ PTP" to 1-833-HYRIMOZ to enroll
- They will need to **submit a photo** of their pharmacy receipt **OR** medication label **OR** prescription history from an insurance or pharmacy platform
 - Photo must include:
 - Patient name
 - Date of fill (must be filled within the last 90 days)
 - HYRIMOZ or adalimumab-adaz medication name
- Once their eligibility has been verified, they will receive a healthcare debit card in the mail

"The HYRIMOZ" Patient Transition Program provides a one-time reimbursement of costs to patients who transition from Humira" to HYRIMOZ, in the form of a \$200 debit card that the patient must certify will be used for healthcare-related expenses. The following are acceptable merchant codes at which the debit cards can be used: 5912 DRUG STORES, PHARMACIES; 8011 DOCTORS — NOT ELSEWHERE CLASSIFIED; 8050 NURSING AND PERSONAL CARE FACILITIES; 8062 HOSPITALS; 8071 DENTAL AND MEDICAL LABORATORIES; and 8099 HEALTH PRACTITIONERS/MED SVCS UNCLASSIFIED. To qualify, a patient must provide proof of a filled HYRIMOZ prescription for an approved indication dated no more than 90 days prior to applying for the Patient Transition Program. Residents of Illinois, Massachusetts, Michigan, Minnesota, Mississippi, and Rhode Island are not eligible. A patient is not eligible if the patient's prescription is paid for, in whole or in part, by any state or federally funded programs, including but not limited to Medicare (including Part D, even in the coverage gap) or Medicaid, Medigap, VA, DOD, or TRICARE, or private indemnity, or HMO insurance plans that reimburse the patient for the entire cost of the patient's prescription drugs, or where prohibited by law. Sandoz reserves the right to rescind, revoke, or amend this offer at any time and without further notice.



Important Safety Information

IMPORTANT SAFETY INFORMATION (cont'd): WARNINGS AND PRECAUTIONS (cont'd)

Malignancies (cont'd)

- Consider the risks and benefits of TNF blocker-treatment, including HYRIMOZ®, prior to initiating therapy in patients with known malignancy
- Non-melanoma skin cancer (NMSC) was reported during clinical trials for adalimumab-treated patients. Examine all patients, particularly those with a history of prolonged immunosuppressant or PUVA therapy for the presence of NMSC prior to and during treatment with HYRIMOZ
- In the adalimumab clinical trials there was an approximate 3-fold higher rate of lymphoma than
 expected in the general US population. Patients with chronic inflammatory diseases, particularly
 those with highly active disease and/or chronic exposure to immunosuppressant therapies, may
 be at a higher risk than the general population for the development of lymphoma, even in the
 absence of TNF blockers
- Post-marketing cases of acute and chronic leukemia have been reported in association with TNF-blocker use. Approximately half of the post-marketing cases of malignancies in children, adolescents, and young adults receiving TNF blockers were lymphomas; other cases represented a variety of different malignancies and included rare malignancies usually associated with immunosuppression and malignancies that are not usually observed in children and adolescents

Hypersensitivity Reactions

 Anaphylaxis or serious allergic reactions have been reported following administration of adalimumab products. If an anaphylactic or other serious hypersensitivity reaction occurs, immediately discontinue administration of HYRIMOZ and institute appropriate therapy

Hepatitis B Virus Reactivation

- Use of TNF blockers, including HYRIMOZ, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal
- Evaluate patients at risk for HBV infection for prior evidence of HBV infection before initiating TNF blocker therapy
- Exercise caution in patients identified as carriers of HBV and closely monitor during and after HYRIMOZ treatment
- In patients who develop HBV reactivation, stop HYRIMOZ and initiate effective anti-viral therapy. Exercise caution when resuming HYRIMOZ after HBV treatment

Neurologic Reactions

- Use of TNF-blocking agents, including adalimumab products, has been associated with rare cases
 of new onset or exacerbation of central nervous system and peripheral demyelinating disease,
 including multiple sclerosis (MS), optic neuritis, and Guillain-Barré syndrome
- Exercise caution when considering HYRIMOZ for patients with these disorders; discontinuation of HYRIMOZ should be considered if any of these disorders develop
- There is a known association between intermediate uveitis and central demyelinating disorders

Hematological Reactions

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF-blocking agents. Medically significant cytopenia has been infrequently reported with adalimumab products
- Consider stopping HYRIMOZ if significant hematologic abnormalities occur

Heart Failure

 Worsening and new onset congestive heart failure (CHF) has been reported with TNF blockers. Cases of worsening CHF have also been observed with adalimumab products; exercise caution and monitor carefully



Important Safety Information

IMPORTANT SAFETY INFORMATION (cont'd): WARNINGS AND PRECAUTIONS (cont'd)

Autoimmunity

 Treatment with adalimumab products may result in the formation of autoantibodies and, rarely, in the development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop

Immunizations

- Patients on HYRIMOZ® should not receive live vaccines
- · Pediatric patients, if possible, should be brought up to date with all immunizations prior to initiating HYRIMOZ therapy
- Adalimumab is actively transferred across the placenta during the third trimester of pregnancy and may affect immune response in the in utero exposed infant. The safety of administering live or live-attenuated vaccines in infants exposed to adalimumab products in utero is unknown. Risks and benefits should be considered prior to vaccinating (live or live-attenuated) exposed infants

ADVERSE REACTIONS

The most common adverse reactions (incidence >10 %): infections (eg, upper respiratory, sinusitis), injection site reactions, headache, and rash.

Please see full Prescribing Information for HYRIMOZ, including Boxed Warning and Medication Guide.

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATIONS: HYRIMOZ® (adalimumab-adaz) injection for subcutaneous use, a prescription medication, is a tumor necrosis factor (TNF)-blocker indicated for:

- · Rheumatoid Arthritis (RA): Alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs), for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA
- · Juvenile Idiopathic Arthritis (IIA): Alone or in combination with methotrexate for reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older
- · Psoriatic Arthritis (PsA): Alone or in combination with non-biologic DMARDs, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA
- Ankylosing Spondylitis (AS): Reducing signs and symptoms in adult patients with active AS
- · Crohn's Disease (CD): Treatment of moderately to severely active CD in adults and pediatric patients 6 years of age and older
- · Ulcerative Colitis (UC): Treatment of moderately to severely active UC in adult patients <u>Limitations of use:</u> The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF blockers

References: 1. Data on file. PsA PB Feb 2024 HYRIMOZ preferred. Sandoz Inc. March 2024. 2. Data on file. IGVIA MIDAS based on an analysis of volume of worldwide sales (in KG) for the period of March to August 2022. Not all products surveyed were available in all listed countries. Sandoz Inc. October 2022.
3. Data on file. Based on data outside the US from January to December 2023. PSUR data. Sandoz Inc. March 2024. 4. Data on file. Commercial Market Access. Sandoz Inc. February 2023. 5. HYRIMOZ prescribing information. Princeton, NJ; Sandoz Inc. 6. Humira® prescribing information. North Chicago, IL: AbbVie Inc. 7. Data on file. Adalimumab pricing compendia listings. Sandoz Inc. July 2023. 8. Nabi H, Georgiadis S, Loft AG, et al. Comparative effectiveness of two adalimumab biosimilars in 1318 real-world patients with inflammatory rheumatic disease mandated to switch from originator adalimumab: nationwide observational study emulating a randomised clinical trial. Ann Rheum Dis. 2021;80(11):1400-1409. doi:10.1136/annrheumdis-2021-219951 9. Loft N, Egeberg A, Rasmussen MK, et al. Outcomes following a mandatory nonmedical switch from adalimumab originator to adalimumab biosimilars in patients with psoriasis. JAMA Dermatol. 2021;157(6):676-683. doi:10.1001/jamadermatol.2021.0221

10. AbbVie. ClinicalTrials.gov. Updated June 25, 2019. Accessed March 4, 2024. https://www.clinicaltrials.gov/search?term=humira 11. Sandoz website. Biosimilars for better. Accessed March 4, 2024. https://www.sandoz.com/business/biosimilars/ 12. Jeremias S. FDA approves Avzivi, the fifth biosimilar to Avastatin. The American Journal of Managed Care/The Centers for Biosimilars. December 19, 2023. Accessed March 4, 2024. https://www.centerforbiosimilars.com/view/fda-approved-avzivi-the-fifth-biosimilar-to-avastin 13. FDA-approved biosimilars. Biosimilars Council. September 20, 2021. Accessed March 4, 2024.

https://biosimilarscouncil.org/resource/fda-approved-biosimilars

adalimumab-adaz 40 mg/0.4 mL for injection

Sandoz is a pioneer and global leader of biosimilar development

We have unparalleled biosimilar experience that includes:

years as a leader in biosimilar development¹¹

FDA-approved biosimilars in the United States^{12,13}

25 molecules in development¹¹

Sandoz has the experience you want in a biosimilar manufacturer...





Team HYRIMOZ® is here for you



Contact your **HYRIMOZ Immunology Sales Specialist** for questions related to:

- Clinical information
 - Efficacy and safety
 - Indications
 - Dosing
 - Administration
 - Samples

- · Insurance coverage
- In-office educational resources
- Sandoz One Source patient support programs



Contact your **HYRIMOZ Field Reimbursement Manager** for questions related to:

 Patient-level^a reimbursement support

Patient-level^a insurance

coverage

- In-office educational materials
- Sandoz One Source patient support programs



You can also contact a **Sandoz Medical Science Liaison** if you would like more information about the science behind biosimilars or HYRIMOZ.

^aPatient consent must be on file.





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INDICATIONS (cont'd)

- Plaque Psoriasis (Ps): Treatment of adult patients with moderate to severe chronic Ps who
 are candidates for systemic therapy or phototherapy, and when other systemic therapies are
 medically less appropriate. HYRIMOZ should only be administered to patients who will be
 closely monitored and have regular follow-up visits with a physician
- · Hidradenitis Suppurativa (HS): Treatment of moderate to severe HS in adults
- Uveitis: Treatment of non-infectious intermediate, posterior, and panuveitis in adults

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Patients treated with adalimumab products, including HYRIMOZ, are at increased risk for developing serious infections that may lead to hospitalization or death.

Full Boxed Warning shown on pages 1-3.

Please see Important Safety Information throughout and full <u>Prescribing Information</u> for HYRIMOZ, including Boxed Warning and Medication Guide.

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