HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use HYRIMOZ™ safely and effectively. See full prescribing information for HYRIMOZ .

HYRIMOZ (adalimumab-adaz) injection, for subcutaneous use
Initial U.S. Approval: 2018

HYRIMOZ (adalimumab-adaz) is biosimilar* to HUMIRA (adalimumab)

WARNING: SERIOUS INFECTIONS AND MALIGNANCY

See full prescribing information for complete boxed warning.

SERIOUS INFECTIONS (5.1, 6.1):

- **Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens.**
- **Discontinue HYRIMOZ if a patient develops a serious infection or sepsis during treatment.**
- **Perform test for latent TB; if positive, start treatment for TB prior to starting HYRIMOZ.**
- **Monitor all patients for active TB during treatment, even if initial latent TB test is negative.**

MALIGNANCY (5.2):

- **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 occurred in adolescent and young adults with inflammatory bowel disease treated with TNF-blockers including adalimumab products.**

----------INDICATIONS AND USAGE----------

HYRIMOZ is a tumor necrosis factor (TNF)-blocker indicated for treatment of:

- **Rheumatoid Arthritis (RA) (1.1):** 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 (JIA) (1.2):** Reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 4 years of age and older.
- **Psoriatic Arthritis (PsA) (1.3):** Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA.
- **Ankylosing Spondylitis (AS) (1.4):** Reducing signs and symptoms in adult patients with active AS.
- **Adult Crohn's Disease (CD) (1.5):** Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's Disease who have had an inadequate response to conventional therapy. Reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.
- **Ulcerative Colitis (UC) (1.7):** Inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP). The effectiveness of HYRIMOZ has not been established in patients who have lost response to or were intolerant to TNF-blockers.
- **Plaque Psoriasis (Ps) (1.8):** The treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

----------DOSAGE AND ADMINISTRATION----------

- Administered by subcutaneous injection (2)

Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis (2.1):

- 40 mg every other week.
  - Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week.

Juvenile Idiopathic Arthritis (2.2):

- *≥ 30 kg (66 lbs):* 40 mg every other week

Adult Crohn's Disease and Ulcerative Colitis (2.3, 2.5):

- Initial dose (Day 1): 160 mg (four 40 mg injections in one day or two 40 mg injections per day for two consecutive days)
- Second dose two weeks later (Day 15): 80 mg
  - Two weeks later (Day 29): Begin a maintenance dose of 40 mg every other week.
- For patients with Ulcerative Colitis only: Only continue HYRIMOZ in patients who have shown evidence of clinical remission by eight weeks (Day 57) of therapy.

Plaque Psoriasis (2.6):

- 80 mg initial dose, followed by 40 mg every other week starting one week after initial dose.

----------DOSAGE FORMS AND STRENGTHS----------

- Injection: 40 mg/0.8 mL in a single-dose pre-filled glass syringe (with BD UltraSafe Passive™ Needle Guard) (3)
- Injection: 40 mg/0.8 mL in a single-dose pre-filled pen (Sensoready® Pen) (3)

----------CONTRAINDICATIONS----------

None (4)

----------WARNINGS AND PRECAUTIONS----------

- *Serious infections:* Do not start HYRIMOZ during an active infection. If an infection develops, monitor carefully, and stop HYRIMOZ if infection becomes serious (5.1)
- *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 (5.1)
- *Malignancies:* Incidence of malignancies was greater in adalimumab - treated patients than in controls (5.2)
- *Anaphylaxis or serious allergic reactions* may occur (5.3)
- *Hepatitis B virus reactivation:* Monitor HBV carriers during and several months after therapy. If reactivation occurs, stop HYRIMOZ and begin anti-viral therapy (5.4)
- Demyelinating disease: Exacerbation or new onset, may occur (5.5)
- *Cytopenias, pancytopenia:* Advise patients to seek immediate medical attention if symptoms develop, and consider stopping HYRIMOZ (5.6)
- *Heart failure:* Worsening or new onset, may occur (5.8)
- *Lupus-like syndrome:* Stop HYRIMOZ if syndrome develops (5.9)

----------ADVERSE REACTIONS----------

Most common adverse reactions (incidence > 10 %): infections (e.g. upper respiratory, sinusitis), injection site reactions, headache and rash (6.1)

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

----------DRUG INTERACTIONS----------

- *Abatacept:* Increased risk of serious infection (5.1, 5.11, 7.2)
- *Anakinra:* Increased risk of serious infection (5.1, 5.7, 7.2)
- *Live vaccines:* Avoid use with HYRIMOZ (5.10, 7.3)

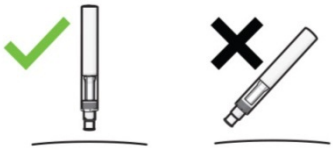
See 17 for PATIENT COUNSELING INFORMATION and Medication Guide

***** Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of HYRIMOZ has been demonstrated for the condition(s) of use (e.g. indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information.

Revised: **02/2021**

4. Holding your Sensoready Pen

- Hold your Sensoready Pen at 90 degrees to the cleaned injection site (see **Figure G**).



Correct **Incorrect**

Figure G: hold your pen

Your injection

You must read this before injecting
During the injection you will hear **2 loud clicks**:

- The **first click** indicates that the injection has **started**.
- Several seconds later a **second click** will indicate that the injection is **almost** finished.

You **must** keep holding your Sensoready® Pen firmly against your skin until you see a **green indicator** fill the window and stop moving.

5. Starting your injection

- Press your Sensoready Pen firmly against the skin to start the injection (see **Figure H**).
- The first click indicates the injection has started.
- Keep holding your Sensoready Pen firmly against your skin.
- The green indicator shows the progress of the injection.

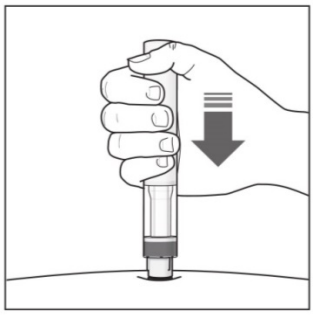


Figure H: start your injection

6. Completing your injection

- Listen for the second click. This indicates the injection is almost complete.
- Check that the green indicator fills the window and has stopped moving (see **Figure I**).
- The Sensoready Pen can now be removed.

Figure I: complete your injection

After your injection

7. Check that the green indicator fills the window (see **Figure J**)

- This means the medicine has been delivered. Contact your doctor if the green indicator is not visible.
- There may be a small amount of blood at the injection site. You can press a cotton ball or gauze over the injection site and hold it for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if needed.

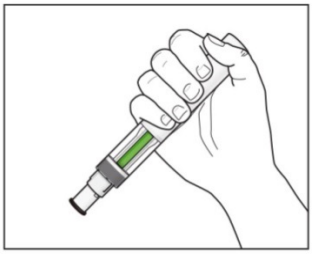


Figure J: check the green indicator

8. Disposing of used Sensoready® Pens

- Put your used Sensoready Pen in a FDA-cleared sharps disposal container right away after use (see **Figure K**). Do not throw away (dispose of) any Sensoready Pens in your household trash.
- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
  - made of a heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - upright and stable during use,
  - leak resistant, and
  - properly labeled to warn of hazardous waste inside the container.
- When your sharps container is almost full, you will need to follow your community guidelines, for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used syringes, needles and pens. For more information about safe sharps disposal, and for specific information about sharps disposal, in the state that you live in, go to FDA's website at:

  www.fda.gov/safesharpsdisposal
- Do not dispose your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

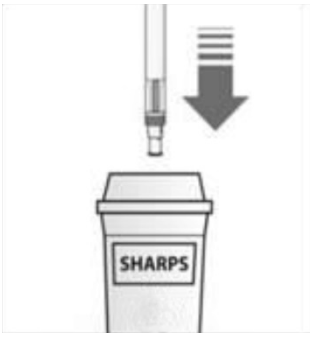


Figure K: dispose of your used pen

SANDOZ A Novartis Division

Manufactured by:

Sandoz Inc.

Princeton, NJ 08540

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Made in Austria & U.S.A.

This Instructions for Use has been approved by the U.S. Food and Drug Administration

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