Hyrimoz adalimumab | XPOSE® by SANDOZ Patient Support Program

XPOSE® by Sandoz Patient Support Program Enrollment and Consent Form

For patients prescribed HYRIMOZ® (adalimumab)

Telephone: 1-888-449-7673
Fax: 1-844-449-7673
Monday–Friday: 8 AM–8 PM EST

Type of patient

☐ **Transition** _____ ☐ **New** ☐ **Renewal**
Expiry date on public plan if applicable

Patient information and consent (please print)

First name _____ Last name _____

Sex: ☐ M ☐ F ☐ Other

Date of birth (DD/MM/YYYY) _____

Health card # _____

Address _____

City _____ Province _____ Postal code _____

Primary phone number: ☐ Cell phone ☐ Home phone Secondary phone number: ☐ Cell phone ☐ Home phone

Leave a voice or text message on primary and secondary number: ☐ Yes ☐ No

Language: ☐ English ☐ French ☐ Other _____

Email _____

I consent to receive emails related to the Program.
You will have the ability to withdraw your consent at any time in the future.

☐ I agree to be contacted for market research purposes and studies.

☐ I (the patient or parent/guardian of the patient) have read and agree to the patient consent on the second page of this form (please sign below).

☐ I (the patient or parent/guardian of the patient) consent to be contacted by the XPOSE® by Sandoz Patient Support Program (please sign below).

☐ Verbal consent received by: _____

X Patient signature or parent/guardian signature (if the patient is under 18 years old) or person who has received verbal consent signature

Date (DD/MM/YYYY) _____

Referring physician and clinic information (please print)

Physician name _____

Physician phone # _____ Fax # _____

License # _____

Address _____

City _____ Province _____ Postal code _____

Clinic contact _____

Contact email _____

Preferred form of communication: ☐ Email ☐ Fax ☐ Phone

Pharmacy services (optional)

Indicate if the patient has a preferred pharmacy provider _____

Rx provided to: ☐ Pharmacy ☐ Patient

Injection/education services (optional)

☐ Injection/education training ☐ Biosimilar education ☐ None required

Screening/testing

☐ I confirm that TB testing has been completed for the patient and they can start treatment.

Do you require the Program to schedule screening or testing on your behalf?

☐ TB QuantiFERON
☐ TB skin test
☐ Fecal calprotectin ☐ Reschedule: every __ months
☐ TDM ☐ Reschedule: every __ months
☐ Other tests required:_____ ☐ Reschedule: every __ months ☐ None required

Rx and physician signature: All sections REQUIRED

☐ **HYRIMOZ® Pre-filled syringe (20 mg in 0.4 mL sterile solution)**
☐ **HYRIMOZ® Pre-filled syringe (40 mg in 0.8 mL sterile solution)**
☐ **HYRIMOZ® Pre-filled SensoReady® Pen (40 mg in 0.8 mL)**

☐ **Rheumatoid Arthritis (RA)**
40 mg administered every other week subcutaneously (sc)

☐ **Psoriatic Arthritis (PsA)**
40 mg administered every other week (sc)

☐ **Ankylosing Spondylitis (AS)**
40 mg administered every other week (sc)

☐ **Plaque Psoriasis (PsO)**
Week 0=80 mg, then 40 mg every other week, beginning Week 1 (sc)

☐ **Adult Crohn's Disease (CD)**
Week 0=160 mg, Week 2=80 mg, then 40 mg every other week, beginning at Week 4 (sc)

☐ **Ulcerative Colitis (UC)**
Week 0=160 mg, Week 2=80 mg, then 40 mg every other week, beginning at Week 4 (sc)

☐ **Hidradenitis Suppurativa (HS)**
Week 0=160 mg, Week 2=80 mg, then 40 mg every week, beginning at Week 4 (sc)

☐ **Uveitis**
Week 0=80 mg, then 40 mg every other week, beginning Week 1 (sc)

☐ **Polyarticular Juvenile Idiopathic Arthritis (JIA)***
☐ For patients that weigh 10 kg to <30 kg, 20 mg every other week (sc)
☐ For patients that weigh ≥30 kg, 40 mg every other week (sc)

☐ **Dosing escalation** (specify, if applicable): _____

Duration of prescription: ☐ 12 months ☐ 6 months ☐ 3 months **Other:** _____

Therapy initiation

☐ Start treatment immediately
☐ Start date: _____ (DD/MM/YYYY)

HYRIMOZ®
Number of doses provided: ☐

Other instructions

I have read and agree to the physician declaration on the second page of this form.

I certify that this prescription order is an original prescription. The designated pharmacy is the only recipient. The original will not be reused.

X Physician signature

Date (DD/MM/YYYY) _____

* A dose of 10 mg every other week can be considered for patients weighing 10 to <15 kg. A different adalimumab product should be considered as there are no available presentations of HYRIMOZ® capable of delivering 10 mg.
For full dosing and administration information, see the Product Monograph.

Please fax the completed form to the XPOSE® by Sandoz Patient Support Program at 1-844-449-7673.

Physician Declaration

I have read the patient consent section of this form and confirm: (1) I agree to my patient being enrolled in the XPOSE® by Sandoz Patient Support Program ("Program"); (2) I have prescribed the drug specified on this form in accordance with its product monograph; and (3) I have the patient's express consent to provide the Program with the information in this form and any other information relevant to provide the Program's services.

I accept that my information, including Personal Information, may be used by Sandoz Canada Inc. ("Sandoz") or its agents for reasons related to improving, monitoring and auditing its programs, for commercial or market research purposes, or as otherwise permitted by law. Details about how my file will be maintained, and how to access/correct my information, are as set out in the patient consent section.

I acknowledge that adverse events may be reported about my patients participating in the Program and understand I may be contacted by Sandoz or its agents to provide follow-up information. As adverse event reports may need to be processed in and outside of Canada and forwarded to Canadian and foreign regulatory authorities, I understand that my information may be stored or processed outside of Canada.

I have discussed the Program with the patient who wishes to enroll and has agreed that I share their Personal Information to the Program to contact the patient and confirm enrollment.

I certify that this prescription order is an original prescription. The designated pharmacy is the only recipient. The original will not be reused.

Patient Consent

What is the XPOSE® by Sandoz Patient Support Program?

XPOSE® by Sandoz Patient Support Program is a patient support program ("Program") provided by Sandoz Canada Inc. and/or its affiliates (collectively "Sandoz", "we", "us", "our") to Canadian patients who have been prescribed HYRIMOZ®. Your healthcare professional believes you could benefit from the Program. The Program services may include health/product information, insurance reimbursement assistance or treatment-related services such as injection training and support (the "Services").

A third-party service provider is the administrator of the Program: its employees and/or agents handle your Personal Information, which is processed in accordance with privacy laws and Sandoz privacy/data protection standards. You will be notified should the administrator of the Program change, including in the case of administration by a Sandoz department; your Personal Information will continue to be protected with equivalent safeguards.

Your participation in the Program is voluntary. If you choose not to participate, neither your medical treatment nor your insurance coverage eligibility will be impacted. However, if you do not participate, you cannot receive assistance or Services from the Program. The Program is not intended to provide medical advice or medical diagnoses. You agree to seek the advice of your physician or other qualified healthcare professional if you have health concerns, and not to disregard professional medical advice based on information obtained from the Program. Sandoz reserves the right to modify or terminate the Program at any time without prior notice.

In the event that you elect to benefit from any external support referral service offered by the Program to help you locate available resources in your community (including injection training at a community pharmacy), you understand that the third parties to whom you may be referred by the Program are in no way affiliated with, or monitored by, Sandoz. You understand that you are solely responsible for your interactions with these third parties and Sandoz cannot be held responsible for the information or services that these third parties may offer to you.

Why is Personal Information collected, for which purposes and with whom could it be shared?

Information, such as your date of birth, contact information, drug/medical, and insurance/financial information (collectively "Personal Information") is collected to communicate with you, provide you with the Programs Services, audit or monitor the Program, and perform certain activities as required or permitted by law, including to process and report adverse events ("AEs"). We may contact you at the contact information you have provided; e-mail, phone or other (if via cellular, we will not assume any resulting cellular phone charges). E-mail and text may not be secure methods of communication. Only relevant personnel will have access to your Personal Information.

Your Personal Information may be collected from and disclosed to healthcare professionals, insurance providers or other third parties, as needed for the Program's administration and Services. Our third-party providers are contractually obliged to strict data protection and security requirements.

In the case of AE processing and reporting to regulatory authorities, if monitoring or auditing is performed, or if required and/or permitted by law, it may be that Sandoz employees or agents will have access to your Personal Information.

The Administrator or Sandoz agents may de-identify, aggregate (combine with other data) and/or anonymize your Personal Information to conduct analyses for commercial, research/publication purposes or to improve the Program. Your Personal Information may be stored or processed outside of Canada, including for AE processing and reporting requirements. In such case, Sandoz ensures that your Personal Information is protected. Your Personal Information may be subject to the laws of foreign jurisdictions, with a different level of protection than your country of residence.

What happens if I withdraw from the Program?

You may revoke your consent at any time, by calling the Program at 1-888-449-7673. Withdrawing your consent will result in the termination of your participation in the Program and its Services. No new Personal Information will be collected; the file containing your Personal Information will be maintained during the term of the Program for monitoring and regulatory purposes; and de-identified, aggregated or anonymized data may continue to be used as described above.

You may request access or correction to your file by contacting the XPOSE® by Sandoz Patient Support Program at 1-888-449-7673.

By signing the consent, you agree to the collection, use and disclosure of your Personal Information as described herein. You can learn more about how Sandoz protects privacy at https://www.sandoz.com/privacy-policy

HYRIMOZ® (adalimumab) is indicated for:

- Reducing the signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. HYRIMOZ® can be used alone or in combination with methotrexate (MTX) or other disease-modifying anti-rheumatic drugs (DMARDs).
- In combination with methotrexate, reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients, 2 years of age and older who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs). HYRIMOZ® can be used as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is not appropriate. Adalimumab has not been studied in pediatric patients with polyarticular juvenile idiopathic arthritis aged less than 2 years.
- Reducing the signs and symptoms of active arthritis and inhibiting the progression of structural damage and improving the physical function in adult psoriatic arthritis patients. HYRIMOZ® can be used in combination with methotrexate (MTX) in patients who do not respond adequately to methotrexate alone.
- Reducing signs and symptoms in patients with active ankylosing spondylitis who have had an inadequate response to conventional therapy.
- 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, including corticosteroids and/or immunosuppressants. HYRIMOZ® is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.
- Treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy including corticosteroids and/or azathioprine or 6-mercaptopurine (6-MP) or who are intolerant to such therapies. The efficacy of adalimumab in patients who have lost response to or were intolerant to TNF blockers has not been established.
- Treatment of active moderate to severe hidradenitis suppurativa in adult patients, who have not responded to conventional therapy (including systemic antibiotics).
- Treatment of adult patients with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy. For patients with chronic moderate plaque psoriasis, HYRIMOZ® should be used after phototherapy has been shown to be ineffective or inappropriate.
- Treatment of non-infectious uveitis (intermediate, posterior and panuveitis) in adult patients with inadequate response to corticosteroids or as corticosteroid sparing treatment in corticosteroid-dependent patients.

For more information:

Please consult the HYRIMOZ® Product Monograph at https://www.sandoz.ca/sites/www.sandoz.ca/files/Hyrimoz-Product-Monograph.pdf for complete and important information relating to adverse reactions, drug interactions, dosing, and other information, which have not been discussed in this piece. The Product Monograph is also available by calling Sandoz Canada Inc. at 1-800-343-8839 ext. 4636.

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