XPOSE® Program enrollment and consent form

Please email or fax completed form. Telephone: 1-844-27XPOSE (1-844-279-7673) Fax: 1-866-872-5771
Email: cosentyx@xposeprogram.ca *Unless encrypted, be mindful that email communications may not be safe.* ***One form per email.***

FOR DERMATOLOGY: Moderate to severe plaque psoriasis (PsO) and moderate to severe Hidradenitis Suppurativa (HS)
All sections MUST be completely filled out.

Patient information (please print)

First name _____ Last name _____

Date of birth (DD/MM/YYYY) _____ ☐ Male ☐ Female ☐ Non-binary

Health card number _____ Weight (kg) _____

Legal guardian name (if applicable) _____ Relationship to patient (if applicable) _____

Address _____

City _____ Province _____ Postal code _____

(____) ____ - ____ (____) ____ - ____
Mobile phone Other

Email _____

Patient/legal guardian signature

I would like to be enrolled in the Novartis XPOSE® Program for COSENTYX® (secukinumab). I have read and agree to the Patient Consent on the second page or reverse side of this form.

Patient/legal guardian name _____

X _____ _____
Patient/legal guardian signature Date (DD/MM/YYYY)

If unable to obtain written consent from patient, please document verbal consent.

Name of the person who obtained the verbal consent _____

X _____
Signature of the person who obtained the verbal consent

Relationship to patient _____ Date on which verbal consent was obtained (DD/MM/YYYY) _____

Tuberculosis (TB) screening*†

☐ Completed Date (DD/MM/YYYY) _____ ☐ Required
If required, type:
☐ QuantiFERON
☐ Skin test
Result _____

Chest X-ray† (CXR)

☐ Required ☐ Not required **Test results:†** ☐ Positive ☐ Negative

Prescribing HCP

First name _____ Last name _____

Address _____

City _____ Province _____ Postal code _____ License # _____

Office contact name _____

(____) ____ - ____ (____) ____ - ____
Telephone Fax

Email _____

Preferred mode of communication: ☐ Phone ☐ Email ☐ Fax

Prescribing HCP consent

I have discussed the Patient Support Program ("PSP") with the patient who wishes to enroll and has consented that I share their personal information (name, email, contact number, prescription information) in this form with the PSP to contact the patient and confirm enrollment.

I acknowledge that adverse events may be reported about my patients participating in the PSP and understand I may be contacted by Novartis or its agents to provide follow-up information for processing as disclosed in this consent.

I acknowledge that I have read and understand the information provided on this page and consent to the collection, use, and disclosure of my personal information as detailed in said page.

X _____ _____
Prescribing HCP signature Date (DD/MM/YYYY)

Rx

COSENTYX® format:

☐ **SensoReady® Pen** (auto-injector, not available in 75 mg format)
☐ Pre-filled syringe

Has the patient been initiated on samples? ☐ Yes ☐ No
If yes, how many 150 mg sample doses were provided to the patient? _____

Moderate to severe PsO (adult patients)

New Rx ☐ 300 mg s.c. Renewal ☐ 300 mg s.c.
Duration of treatment: ☐ 3 months ☐ 6 months ☐ 12 months ☐ Other: _____

Induction dose at Weeks 0, 1, 2, 3 and 4.
Maintenance dose:
☐ Monthly ☐ Every 2 weeks (option for patients weighing ≥90 kg)

Moderate to severe PsO (pediatric patients, ≥6 years)

<50 kg

New Rx ☐ 75 mg s.c. (Note: Only pre-filled syringe) Renewal ☐ 75 mg s.c. (Note: Only pre-filled syringe)
Duration of treatment: ☐ 3 months ☐ 6 months ☐ 12 months ☐ Other: _____

≥50 kg

New Rx ☐ 150 mg s.c. Renewal ☐ 150 mg s.c. ☐ 300 mg s.c.
Duration of treatment: ☐ 3 months ☐ 6 months ☐ 12 months ☐ Other: _____

Induction dose at Weeks 0, 1, 2, 3 and 4. Maintenance dose monthly.

Moderate to severe HS

New Rx ☐ 300 mg s.c. Renewal ☐ 300 mg s.c.
Duration of treatment: ☐ 3 months ☐ 6 months ☐ 12 months ☐ Other: _____
Induction dose at Weeks 0, 1, 2, 3 and 4.
Maintenance dose:
☐ Monthly ☐ Every 2 weeks (based on clinical response)

PsO assessment details

BSA (%): _____ PASI: _____ DLQI: _____
☐ Face ☐ Hands ☐ Feet ☐ Genitals
Noted psoriasis manifestations
☐ Nail involvement ☐ Palmoplantar psoriasis ☐ Scalp psoriasis
☐ Other: _____

HS assessment details

Hurley Stage: ☐ Stage II ☐ Stage III
Total # abscesses: _____ Total # nodules: _____
Date taken (DD/MM/YYYY) _____
Lesions in at least 2 (two) distinct anatomic areas, one of which is Hurley Stage II or III
☐ Yes ☐ No
Continuous 3-month trial of oral antibiotics with inadequate response? ☐ Yes ☐ No

Previous therapies – HS and PsO

☐ Biologic therapy: _____
☐ Topicals
☐ Phototherapy
☐ Oral systemic: _____
☐ Other: _____

Directives from the prescribing HCP

Patient is cleared to start therapy: ☐ Yes ☐ No
Notes: _____

Prescribing HCP signature

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

X _____ _____
Prescribing HCP signature Date (DD/MM/YYYY)

* This service will only be offered in provinces where there is no provincial access. † Specific TB results will be reported back to the requester by the Program. Any follow-up on positive TB is at the discretion/responsibility of the requester.

XPOSE® Program enrollment and consent form

Have your patients take a photo to access **COSENTYX.ca** for more information.
The Drug Identification Number (DIN) 02438070 is needed to sign in.

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Recommended dose:

- **300 mg (2 x 150 mg) for adults with moderate to severe PsO**
  - Maintenance dose of 300 mg every 2 weeks may provide additional benefit for adult patients with a body weight of 90 kg or higher.
- **75 mg for patients weighing <50 kg and 150 mg for patients weighing ≥50 kg for pediatric patients (≥6 years) with moderate to severe PsO**
  - Maintenance dose may be increased to 300 mg in pediatric patients (≥6 years, ≥50 kg), as they may derive additional benefit from the higher dose.
- **300 mg (2 x 150 mg) for adults with moderate to severe HS**
  - Maintenance dose of 300 mg every 2 weeks may be prescribed based on clinical response.

COSENTYX® is intended for use under the guidance of a health care professional. Patients may self-inject after proper training and when deemed appropriate. Prescribers are advised to periodically reassess the need for continued therapy.

Patient consent

I would like to be enrolled in the Novartis XPOSE® Program.

I have read and agree to the information provided on this page.
The Program may wish to contact me via electronic means; I will have the opportunity to opt out from such communications.

Privacy Notice

Welcome to the Novartis Pharmaceuticals Canada Inc. ("Novartis", "we") XPOSE® Program.

What is a patient support program ("PSP")?

A PSP is a program to provide assistance to patients, health care professionals ("HCPs") and caregivers. This assistance can take the form of individualized services like:

- Drug treatment/disease information
- Following up with HCPs on their patients
- Reimbursement assistance for a drug treatment
- Travelling assistance to patients where the treatment requires a stay far from their home

The XPOSE® Program offers the following services (non-exhaustive): enrolment, welcome call (48 hours or less), reimbursement navigation, drug delivery, copay assistance, injection services (in certain cases where required), regular proactive touchpoints, and medication tips.

The PSP services are available to any patient meeting the eligibility requirements for enrolment, which typically consist at minimum in a prescription for a drug treatment from an HCP as well as current eligibility under a federal or provincial health insurance plan.

The PSP is not intended to provide medical advice or to replace any professional medical advice provided by a physician or other HCP. Novartis provides the PSP at its discretion and reserves the right to modify or terminate it at any time without prior notice.

CONSENT TO THE PERSONAL INFORMATION COLLECTION

(more specific information is provided in the section "Details")

Why do we collect personal information to run the PSP?

To provide the services Novartis has to collect personal information of patients, HCPs and caregivers. Personal information is any information that can identify an individual, directly (like a name or medical insurance number) or indirectly (by having enough different elements to know who it is).

Which type of personal information is collected?

Personal information connected to the services.

If you are a patient, personal information collected includes only what is needed to provide you the benefits of the PSP: your name, physical and email address, telephone numbers, date of birth, health information such as disease information and the name of your caregiver.

If you are an HCP, personal information collected includes: your name, physical and email address, number of patients enrolled in the PSP. This information can be connected to the information of your patients.

If you are a caregiver, legal guardian, personal information collected includes: your name, physical and email address, telephone numbers.

Who collects the personal information and who has access to it?

The administrator of the PSP, Novartis or the company designated by Novartis, collects the personal information, stores it in a secured database and has access to it to provide the services. The personal information can be shared with HCPs, insurance companies or others to provide the services.

For this XPOSE® Program: the administrator is Innomar Strategies Inc.

Access to the personal information is strictly on the basis of need-to-know for the implementation of the PSP.

Is the personal information transferred outside of the province of residence or Canada?

The personal information is stored in a secured database located in Canada (Alberta, Ontario, or Quebec).

Is the personal information used for other purposes than individualized services?

Yes, other than the individualized services, the personal information collected for the services can serve to do various analyses.

Is any other personal information not connected to a PSP service collected?

No, only with an additional and optional patient consent can some other patient personal information — not connected to a PSP service — be collected.

How to request access to your personal information in the PSP

For questions on your personal information, if you wish to access your file or to withdraw your consent, you can reach the Novartis Privacy Officer at privacy.pharmacanada@novartis.com or XPOSE® Program at 1-844-279-7673.

How to withdraw consent from the PSP

You can withdraw your consent at any time but, without this consent, it may be impossible to provide the services. Withdrawal of consent means that personal information cannot be used in the future and no new personal information will be collected but, personal information already collected will remain in the database or in the Novartis adverse events database until it can be deleted in accordance with requirements to comply with guidelines from health authorities.

When registering to the PSP, as part of its service, we will notify you via email or via text message at the email address or cellular phone number you have shared with us to inform and notify you of the PSP services. You will always have the ability to opt out of these communications, however, opting out of these communications may impact your ability to fully use and experience the PSP services.

DETAILS ON HOW WE COLLECT, USE AND SHARE PERSONAL INFORMATION FOR THE OPERATIONS OF A PSP

Why do we collect personal information to run the PSP?

Personal information is needed to confirm and manage the prescription and to communicate to health care professionals on the treatment and patient care. It is also needed to make sure we are connecting with the right patient and/or caregiver. It is required when reaching to insurance companies to process a request to reimburse the drug or to other individuals or organizations providing a service part of the program.

Here are examples of uses of your personal information for the program:

If you are a patient:

- To reach out to you via phone, mail or email
- To discuss with your health care professional your treatment and drug
- To give you certain program services like injection training and connecting you with laboratories performing medical tests
- If the PSP is offering travelling assistance to you, to book travelling arrangements for you if you have to travel for your treatment

If you are a health care professional:

- To confirm the patient prescription
- To reach out to you regarding your patient treatment and care
- To give you certain program services like sending you your patient's medical tests results

If you are a legal guardian or caregiver:

- To reach out to you to discuss the patient treatment and care
- To book travelling arrangements for you if you have to travel with the patient for the treatment, if this is a service offered by the PSP

Who collects the personal information, who has access to it, how is it protected?

The personal information is collected by the administrator of the program. This administrator is Novartis or a company acting for Novartis. The administrator stores the personal information in a secured database.

Personal information is protected by security measures like:

- encryption (turning the personal information into a secret code)
- restriction on access to the database (with individual usernames and passwords)

Only authorized personnel can access personal information based on their roles and need-to-know for the provision of the services.

Examples of this personnel are:

- agents of the call centre who speak to patients and HCPs and manage PSP requests
- PSP HCPs providing drug treatment training services to patients
- PSP personnel supervising the program activities and/or handling requests or complaints

When services are provided by individuals or companies other than the administrator, they have to protect the personal information in the same manner. For example, drug reimbursement specialists or travelling agency personnel.

Because Novartis supervises the PSP activities, can perform audits and handles adverse events that have to be reported by law: Novartis personnel can have access to the personal information for these purposes (even if it is not the administrator of the PSP). Also, any entity who the law allows could have access to your personal information.

Can the personal information be transferred outside of the individuals' province of residence or of Canada?

The personal information can be transferred outside of your province of residence or of Canada when:

- it is stored in a database by the administrator outside of your province of residence or country as mentioned in the main consent
- information has to be given to health authorities across the world on an adverse event connected to the PSP. If the personal information is not needed, the transfer will not include any identifying information like your name or code that could be linked to you.

The personal information is used for what other purposes?

The personal information can be used to do various types of manual or digital analysis and statistics:

- monitor the program including the delays to enrol/to receive treatment
- monitor the quality of the customer service and of all PSP services
- compile information on how the treatment is taken and the disease is managed by patients
- with the HCP's consent connecting HCP data files (PSP dataset and other Novartis sources) to evaluate the way Novartis reaches out to them for offers

These analyses allow Novartis to create and improve its offers and services to patients and HCPs, like disease awareness campaigns, patient brochures and drug information for HCPs. Only when it is needed is the personal information collected and kept for these analyses and the results. In the majority of the cases, the information is de-identified (replacing identifying data with a code or label) or anonymized for and during the analysis.

Is any other personal information not connected to a PSP service collected?

No, unless for patients for which we have obtained an additional and optional patient consent to collect and use personal information to advance the knowledge and data on drug, treatment or disease. The analyses conducted may not benefit patients or HCPs personally but is of value to Novartis, the health care community, health authorities and the patient community.

I withdraw my consent: what happens next?

It may be impossible for us to provide the services. Withdrawal of consent means that personal information cannot be used in the future and no new personal information will be collected but, personal information already collected will remain in the database or in the Novartis adverse events database until it can be deleted in accordance with requirements to comply with guidelines from health authorities.

COSENTYX® (secukinumab) is indicated for the treatment of:

- Moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy;
- Moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy;
- Adult patients with moderate to severe hidradenitis suppurativa (acne inversa) who have responded inadequately to conventional systemic hidradenitis suppurativa therapy.

Consult the Product Monograph at www.novartis.ca/CosentyxMonograph for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The Product Monograph is also available by calling 1-800-363-8883.

For program-related inquiries, please call or email the XPOSE® Program at:
1-844-27XPOSE (1-844-279-7673)
cosentyx@xposeprogram.ca

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