

PrKOSELUGO™ (selumetinib) Enrolment and Consent Form

This consent form cannot be processed without the physician's signature and any one of the following: (a) the patient's or (b) his/her legal representative's and/or (c) the legal guardian's (if patient is a minor) consent.

Fax **ALL pages** of the completed form to 1-833-569-2436 or email to NF1Support@OneSourcePSP.ca
Please complete **all fields** to minimize delays. For immediate inquiries, please call 1-833-569-2435.

The use of the word "Product" in this form is in reference to KOSELUGO (selumetinib).



SECTION 1: PATIENT/GUARDIAN INFORMATION (patient section)

Patient First Name:		Patient Last Name:	
Date of Birth (DD/MM/YYYY):	Sex: M F Other	Language: En Fr	
Health Card Number:	Patient's weight:		kg
Patient Home Address:			
City:		Province:	
Postal Code:		Email Address:	
Home Phone:		Cell Phone:	
Best time to be reached: Morning Afternoon Evening	May we leave a voicemail or a message with someone who answers? Yes No		
Insurance type: Private Public Unsure	Permission to send text messages Yes No		

LEGAL REPRESENTATIVE/LEGAL GUARDIAN INFORMATION, if applicable

First Name:	Last Name:
Date of birth (DD/MM/YYYY):	Relationship to patient:
Home Address (Street address, City, Province, Postal Code):	

SECTION 2: PATIENT CONSENT (patient section)

SEE FULL PATIENT CONSENT AND PRIVACY INFORMATION SECTION ON PAGE 4. PLEASE ENSURE YOU HAVE READ AND FULLY UNDERSTAND THIS INFORMATION.

I understand that the ONESOURCE® patient support program is sponsored by Alexion Pharma Canada and that a third-party service provider administers the Program on behalf of Alexion for the purpose of assisting Canadian patients with obtaining access to medical treatment. I understand that other service providers may be appointed by Alexion to administer ONESOURCE® from time to time. I also understand that my Personal Information will be processed as described on the last page of this Enrolment Form.

OR Patient and/or his/her legal representative or legal guardian has given verbal consent to proceed with enrolment at this time and the Program Administrator will provide the Patient Consent and Privacy Information at a later date.

Name of Patient/Legal Representative or Guardian

Name of Person Collecting Verbal Consent

Patient/Legal Representative or Guardian Signature

Person Collecting Verbal Consent Signature

Date (DD/MM/YYYY):

Date verbal consent collected (DD/MM/YYYY):





SECTION 3: PRESCRIBING PHYSICIAN INFORMATION (physician section)

First Name:

Last Name:

Clinic Name and Address:

Office Contact Name:

Email:

City:

Province:

Postal Code:

Office Phone:

Office Fax:

SECTION 4: PATIENT ELIGIBILITY (physician section)

I hereby confirm the patient is <18 years of age and is being prescribed KOSELUGO for the treatment of Neurofibromatosis type 1 associated plexiform neurofibromas (as per the Health Canada approved indication)

For the treatment of Neurofibromatosis type 1 (NF1) associated plexiform neurofibromas (PN)

Pediatric patients aged 2 years and above with NF1 who have symptomatic, inoperable PN.

The patient's PN are considered **inoperable**

- Defined as PN that cannot be surgically completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN

AND

The patient's PN are considered **symptomatic**

- Defined as presence of PN-related morbidity, which includes PN-related pain, PN-related disfigurement, and/or PN-related functional disability

Must be completed:

Check the appropriate box(es) below:

Parent diagnosed with NF1? Yes No

Please select all relevant NF1 diagnostic criteria as it relates to the patient.

Must have 2 or more of the criteria or 1 criterion if child of a parent with NF1:

Six or more café-au-lait macules (>5 mm in greatest diameter in prepubertal subjects or >15 mm in greatest diameter in postpubertal subjects)

Freckling in the axillary or inguinal region

Two or more neurofibromas of any type or one plexiform neurofibroma

Optic pathway glioma

Two or more iris Lisch nodules identified by slit lamp examination or two or more choroidal abnormalities

A distinctive bony lesion (dysplasia of the sphenoid bone, anterolateral bowing of the tibia, or pseudarthrosis of a long bone)

A heterozygous pathogenic *NF1* variant with a variant allele fraction of 50% in apparently normal tissue such as white blood cells

NF1 mutation testing performed? Yes No

If yes:

Mutation detected

Mutation not detected

Results pending

Diagnostic Tests:

Date Magnetic Resonance Imaging (MRI) performed (include report):

DD/MM/YYYY

Size of target PN (at least 3 cm):

Location of target PN:

SECTION 5: PRESCRIBING PHYSICIAN AUTHORIZATION (physician section)

I certify that I am the patient's prescribing physician and confirm that the patient has been prescribed the Product as per the Canadian product monograph. This Product has been prescribed for this patient based on my independent medical judgment and the patient's informed consent.

I agree to be contacted by a third party administrator of the Program (the "Program Administrator") about the patient, the Product, the ONESOURCE® Patient Support Program (the "Program") and any adverse events or Product complaints. I consent to the use of my prescribing information for the purpose of administering, monitoring, and assessing the Program. My personal information will be collected, stored and processed for use as described in this informed consent form. Questions regarding Privacy or Compliance may be addressed to the Alexion Canada Privacy Officer at 1004 Middlegate Road, Suite 5000, Mississauga, Ontario L4Y 1M4 or by email at privacy@alexion.com.

I authorize the Program Administrator in the context of the Program to be my designated agent to forward the prescription by fax or other mode of delivery to the pharmacy chosen by the above-named patient. This prescription represents the original prescription drug order.

I agree to keep all confidential information provided to me about the Program in strict confidence and shall not, without Alexion's prior written consent, disclose any confidential information to any third party.

Physician Signature

Date (DD/MM/YYYY)

Please complete all sections in their entirety to ensure accuracy of the submission.

Fax **ALL** pages of the completed form to 1-833-569-2436 or email to NF1Support@OneSourcePSP.ca





SECTION 6: PRESCRIPTION INFORMATION (physician section)



Allergies: None or specify

The recommended dose of KOSELUGO is 25 mg/m² based on body surface area (BSA), taken orally twice daily. Doses should be separated by approximately 12 hours.

Treatment with KOSELUGO should continue as long as clinical benefit is observed, or until PN progression or the development of unacceptable toxicity.

Dosing is individualized based on BSA (mg/m²) and rounded to the nearest achievable 5 mg or 10 mg dose (up to a maximum single dose of 50 mg). Different strengths of KOSELUGO capsules can be combined to attain the desired dose (see Table 1). The recommended dosage for patients with a BSA less than 0.55m² has not been established. See Table 1 below to calculate appropriate dose.

Table 1 - KOSELUGO Recommended Dosage Based on Body Surface Area

Body Surface Area (BSA)	Recommended Dosage (25 mg/m ² BID)		Suggested Supply: 30-day (supplied as 10 mg and 25 mg hard capsules)
0.55 – 0.69 m ²	20 mg in the morning	10 mg in the evening	90 x 10 mg caps
0.70 – 0.89 m ²	20 mg twice daily		120 x 10 mg caps
0.90 – 1.09 m ²	25 mg twice daily		60 x 25 mg caps
1.10 – 1.29 m ²	30 mg twice daily		180 x 10 mg caps
1.30 – 1.49 m ²	35 mg twice daily		60 x 10 mg caps & 60 x 25 mg caps
1.50 – 1.69 m ²	40 mg twice daily		240 x 10 mg caps
1.70 – 1.89 m ²	45 mg twice daily		120 x 10 mg caps & 60 x 25 mg caps
≥1.90 m ²	50 mg twice daily		120 x 25 mg caps

Patient BSA (m²): _____ Recommended Dosage from Table 1: _____ mg BID

Recommended Individualized Dosage*:

KOSELUGO (selumetinib): recommended individualized dose of _____ mg PO twice daily (BID)
(_____ x 25 mg capsules BID / _____ x 10 mg capsules BID)

KOSELUGO should be taken on an empty stomach with no food or drink other than water. The patient should not consume food 2 hours prior to dosing and 1 hour after dosing.

*For further dosing considerations, including dose adjustments, administration, and missed dose information, please refer to the most recent version of the KOSELUGO Product Monograph, available at: <https://www.astrazeneca.ca/en/our-medicines.html>

Quantity: _____ Month(s) Repeat: _____ 30 day supply

Medical Directive:

I approve to start KOSELUGO upon enrolment to the Program

Yes No, pending test results No (other, please specify below)

Licence #:

Physician signature:

Date (DD/MM/YYYY):

Consult the product monograph at <https://www.astrazeneca.ca/en/our-medicines.html> for complete dosing information.

Please complete all sections in their entirety to ensure accuracy of the submission.
Fax ALL pages of the completed form to 1-833-569-2436 or email to Nf1Support@OneSourcePSP.ca



Patient Consent and Privacy Information

ONESOURCE® is the treatment support program for patients. ONESOURCE® provides information, education, and assistance.

The Program is being managed by Alexion Pharma Canada Corp, an AstraZeneca Rare Disease Business Unit ("Alexion") and is administered by an independent third party ("Program Administrator"). Alexion may, at its sole discretion, appoint a new program administrator at any time. By signing this informed consent form, you consent to the transfer of your Personal Information, as well as the prescription itself (if applicable), to any future program administrator, if required.

You understand that the Program is not intended to provide medical advice or medical diagnoses. You should always seek the advice of your physician if you have any health concerns. You have discussed the benefits and risks of the Product with your physician and have decided to start treatment. You understand that (i) it is your right to refuse to sign this consent form, (ii) if you do not give such consent, you will not be provided with access to the Program, and (iii) you do not need to participate in the Program to obtain the Product; however, Alexion and the Program Administrator do not provide support for Product not obtained via the Program.

Alexion reserves the right at any time, without notice, to modify, discontinue or terminate the Program.

By signing this Authorization and Consent, you (or your representative) agree that information that may identify you that is provided to ONESOURCE® by you and/or (1) your physician(s) and other healthcare providers involved in the treatment of your medical condition ("Providers"); (2) the distributor, pharmacy, infusion clinic, or home health agency that supplies or dispenses your medical therapy ("Distributor"); and (3) your health insurer, payor, or patient assistance program ("Payor") (collectively, "Personal Information") will be used to manage and administer ONESOURCE®, including provision of ONESOURCE® services to you as further described below. For these purposes you agree that the Providers, Distributor, and Payor may disclose Personal Information to Alexion Pharma Canada, including, but not limited to, its employees, affiliates, sub-contractors, agents, and other representatives (together, "Alexion"). You understand that your participation in ONESOURCE® is also subject to Alexion's Privacy Notice, available at <https://alexion.com/legal/privacynotice>, which provides you with additional information about Alexion's privacy practices and the privacy rights that may be available to you.

The Personal Information collected, used, or disclosed as part of your participation in ONESOURCE® may include name, address, other contact information, date of birth, diagnoses, medical reports, orders, prescriptions, records, medical histories, findings, prognoses, plans of care and discharge summaries, billing information, insurance claims, utilization review reports, survey responses, and other information you provide in connection with your ONESOURCE® participation. Your Personal Information may be used or disclosed for the following purposes:

Coordination of Care: Between you or your representative, the Provider, Distributor, or Payor for the coordination of your medical care, including therapy adherence reminders.

Disease Management/Patient Education: To provide information, training, and case management services to you or your representative, or any Provider, Distributor, or Payor.

Clinical Research/Treatment Protocols/Meetings: To inform and refer you or your representative of clinical research studies, treatment protocols, disease or program-related surveys, patient advocacy organizations or meetings that may be of interest to you.

Reviewing Your Insurance Coverage/Funding Options: To review, verify, and assist you or your representative in understanding the medications and services that your Payor covers, if you ask and request such service. This may include review of your personal financial information to determine if you qualify for financial assistance which may be available under ONESOURCE®. If you do not qualify for insurance or other coverage to pay for your treatment, your Personal Information and other information may be used to determine if you might qualify in the future for such coverage or to help you identify other sources of payment or financial support.

Billing and Payment: To coordinate the preparation, filing, and processing of health insurance claims, the evaluation of coding (billing) issues, and the resolution or collection of any payment due to Provider, Distributor, Payor or Alexion for your treatment.

Distribution of Therapy: To coordinate the distribution of the medical product to you.

Product Orders: To fulfill medical product orders, answer any questions that you or your representative may have and to inform you about other services that may be of interest to you.

Government Agencies: To provide information as required or requested by representatives of government agencies, review boards, and others who watch over the safety of drugs (or operations) of pharmaceutical manufacturers. AstraZeneca Canada, as the marketing authorization holder for KOSELUGO™, is legally required to report adverse drug events to Health Canada and international health authorities and to monitor product complaints. As such, AstraZeneca Canada, Alexion, their representatives and the Program Administrator may use and report your personal information for these purposes. The Program Administrator or AstraZeneca may contact you or your physician for additional information to fulfill these obligations.

Other Use of Information: To provide you with other ONESOURCE® services that may be in place from time to time, such as a buddy or mentorship program, or otherwise use or disclose your Personal Information with your consent.

Alexion may also remove identifiers from your Personal Information, or combine your Personal Information with the information of others who participate in ONESOURCE® to create aggregated data, and use such data to improve and refine ONESOURCE® and to design and implement other patient programs. Alexion may also use such information for analytics, reporting, and research purposes, including strategy development and the identification of trends such as product utilization, adherence, or outcomes.

Transfer and Processing of Personal Information: To transfer the Personal Information, including between provinces or outside of Canada, for the purposes of communicating the information to Alexion's parent and affiliated entities, and/or for the purposes of storing and processing the information on behalf of Alexion in relation to ONESOURCE®. Your Authorization and Consent serves as explicit consent that your data can be transferred and processed in countries outside Canada, which may not ensure the same level of data protection as provided in Canada, to provide you with the information you requested. The Personal Information will be protected while outside of Canada; however, to the extent required under applicable law, your Personal Information may be accessed by the courts, law enforcement and national security authorities of that other country.

If another service provider is appointed by Alexion to administer ONESOURCE®, your Personal Information will be transferred to this service provider to ensure the continuity of the ONESOURCE® services.

If you have provided your telephone number, the Program services may include Program-related communications (such as appointment reminders) via text messages. You may stop these communications at any time by replying "stop". Charges from your phone plan provider may apply. Even if you stop text messaging communications, you will still be enrolled in the Program until (i) you withdraw, (ii) you are withdrawn because your physician feels it is the right decision or (iii) the Program ends.

This Authorization and Consent may be revoked by you at any time. Please note that if you revoke this Authorization and Consent, your ability to receive ONESOURCE® services may be limited. To revoke your consent, update or access your Personal Information, express a privacy-related concern, or inquire about the privacy practices of ONESOURCE®, you may contact the Alexion Canada Privacy Officer at 1004 Middlegate Road, Suite 5000, Mississauga, Ontario L4Y 1M4 or by email at privacy@alexion.com.

For more information on the Product, please consult the patient medication information section of the product monograph at <https://www.astrazeneca.ca/en/our-medicines.html>

KOSELUGO™ is indicated for the treatment of pediatric patients aged 2 years and above with neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas. Consult the product monograph at <https://www.astrazeneca.ca/en/our-medicines.html> for important information about:

- The most serious warnings and precautions regarding diarrhea and ophthalmologic effects.
- Other relevant warnings and precautions regarding left ventricular ejection fraction, increased creatinine phosphokinase, fatigue, asthenia, skin rash, paronychia and bleeding risk associated with Vitamin E supplementation.
- Conditions of clinical use, adverse reactions, drug interactions and dosing instructions.

The product monograph is also available by calling the AstraZeneca Canada medical information department at 1-800-668-6000.

KOSELUGO™ is a trademark of AstraZeneca AB, used under license by AstraZeneca Canada Inc.

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