Dear patients and colleagues,

The attached Patient Prescriber Agreement Form (PPAF) discusses the risks and benefits of tolvaptan. The form must be completed before beginning treatment.

The purpose of this form is to consent to blood test monitoring that must be done when using tolvaptan. In a recent study of tolvaptan, there were some reports of changes in liver blood tests in people using the drug. As a result, the manufacturer of this drug and Health Canada have created this monitoring program to ensure the drug is being used safely. In BC, we will add an additional safety mechanism by tracking and reviewing this data through the use of our provincial renal database - PROMIS.

Nephrologists across the province have agreed that monitoring allows for safe use of the drug in people who may benefit from tolvaptan.

The Hepatic Safety Monitoring and Distribution Programme is operated by Otsuka and its designated providers, not the BC Renal Agency (BCPRA). That is why these forms are provided by those parties. Although tolvaptan will be distributed through a central pharmacy, monitoring blood tests is the responsibility of your individual nephrologist.

Treatment with tolvaptan is not for everyone with polycystic kidney disease. In a large study, treatment with tolvaptan in a select group of people with polycystic disease slowed the rate of kidney growth. This may slow kidney damage and may delay kidney failure. You have been selected for treatment because your nephrologist's opinion is that you may benefit from treatment and that potential benefit outweighs the risk of side effects, including the ones monitored through this program.

Please refer to the BCPRA website for more information and educational materials regarding the use of tolvaptan in polycystic kidney disease.

Once completed, please fax this form along with the prescription for tolvaptan (a pre-printed order is available on BCPRA website) to Macdonalds Pharmacy, the single distributor of tolvaptan in BC at 1-855-569-0660, and not directly to Otsuka as stated in the following PPAF.

Health Authority Renal Programs
BC Children's Provincial Renal Program, Fraser Health, Interior Health, Island Health, Northern Health, Providence Health Care, Vancouver Coastal Health

BC Renal Agency
An agency of the Provincial Health Services Authority
Suite 700, 1380 Burrard Street
Vancouver, BC V6Z 2H3

Tel 604.875.7340
Fax 604.875.7366
Email bcpra@bcpra.ca
Web www.bcrenalagency.ca

Patient-Prescriber Agreement Form (PPAF)

Please return this completed and signed PPAF by fax to: **1-844-3JINARC (354-6272).**

PRESCRIBER FORM

Pr JINARC™ (tolvaptan) is now available in Canada. JINARC can only be prescribed to patients who have completed and signed this form with their prescriber.

The purpose of this Patient-Prescriber Agreement Form (PPAF) is to document the fully-considered engagement of both the patient and the prescriber to the treatment of autosomal dominant polycystic kidney disease (ADPKD) with JINARC. In accordance with Health Canada requirements, the manufacturer of JINARC has implemented a safety monitoring initiative with regard to use of and access to the JINARC product. This initial step will also serve to confirm the patient enrollment into the Hepatic Safety Monitoring and Distribution Programme ("Programme"). The manufacturer of JINARC is Otsuka Canada Pharmaceutical Inc. (Otsuka). Otsuka is responsible for the Programme and may engage third party service providers to administer the Programme.

JINARC is indicated to slow the progression of kidney enlargement in patients with ADPKD. In ADPKD, kidney enlargement reflects renal cyst burden.

Careful consideration and discussion of the appropriateness of JINARC treatment should be undertaken between the prescriber and patient before initiation of treatment, taking into account the potential benefits and risks of treatment, appropriate patient selection, and the need for mandatory ongoing hepatic function monitoring.

Following mutual agreement to undertake treatment with JINARC, both the patient and their prescriber must complete, sign, and date this PPAF in person, together at the same time. The patient and prescriber must read each statement of their respective section(s) of this PPAF thoroughly, add their initials before each statement confirming that he/she understands the benefits and risks of treatment with JINARC and agrees to comply with the conditions for use prior to initiating JINARC.

Please return all pages of this completed and signed PPAF by fax to: 1-844-3JINARC (354-6272). Incomplete information will result in delay. Please call **1-844-2JINARC (254-6272)** if you have any questions regarding the Programme. A Programme representative will contact the patient to acknowledge and confirm enrollment if the patient provides the required consent as specifically set out herein.

JINARC is only distributed to pharmacies through a unique distributor who will verify with the Programme that there is a signed and valid PPAF on file prior to distributing JINARC. **Should the patient elect to use the services of the Programme Specialty Pharmacy, the prescriber should complete the prescription information section on this form.**

Both the patient and prescriber should keep a copy of the executed PPAF for their records. The PPAF is valid for a period of three (3) years after which time it will need to be renewed. Should the patient's attending prescriber change, this PPAF will need to be renewed. In the event that there are material changes to the Programme, this PPAF or the Product Monograph for JINARC™, the prescriber and the patient will be contacted and informed of such changes.

PRESCRIBER INITIALS	**As the PRESCRIBER of JINARC for the undersigned patient, I acknowledge that:**
	◯ I am a nephrologist or, ◯ I am a physician experienced in the diagnosis and treatment of polycystic kidney disease (ADPKD). Please provide a brief description of your experience/training: _____
	I understand that JINARC is indicated to slow the progression of kidney enlargement in patients with ADPKD. In ADPKD, kidney enlargement reflects renal cyst burden.
	I understand that JINARC is contraindicated in patients: with hypovolemia; with hypernatremia; who cannot perceive or respond to thirst; with clinically relevant impairment of hepatic function; who are anuric; who are pregnant or nursing; or who are hypersensitive to tolvaptan or to any ingredient in the formulation.
	I understand that JINARC has not been studied in pediatric patients (<18 years of age) with ADPKD. Its use is therefore not recommended in this patient population. Also, patients who are anuric, or at, or approaching, end-stage renal disease, would not be expected to benefit from JINARC treatment.
	I understand that the patients most likely to benefit from JINARC treatment appear to be those with rapidly progressive ADPKD, or at a stage of incipient rapid progression, but before widespread destruction of renal architecture has occurred, and I will comply with patient selection criteria as outlined in the totality of the JINARC Product Monograph.
	I have reviewed and understood the risks and potential benefits of JINARC, as well as the requirements of the Hepatic Safety Monitoring and Distribution Programme.
	I have counseled my patient about the potential risks and benefits of JINARC, the criteria for selecting her/him for this treatment, the appropriate use of JINARC, as well as the need for mandatory ongoing hepatic function testing.
	I have provided and reviewed the mandatory JINARC patient educational material with my patient.
	I understand the Hepatic Safety Monitoring and Distribution Programme will send me a liver function status report form for every liver function test required of the patient. I further understand that I, or my delegate(s), must complete, sign and return this report to the Programme in order to ensure that the patient's pharmacy can continue to order and dispense JINARC to my patient. I acknowledge that failure to do so may lead to JINARC supply interruptions for this patient. I understand that the Programme may contact me by phone after sending the liver function status report form to follow up on the availability of pending results for a given month.
	Prior to initiating and prescribing JINARC, I will confirm that my patient's liver function test (i.e., ALT and AST) levels are less than three (3) times the upper limit of normal, and total bilirubin has been assessed.
	I have reviewed the "Prescriber Privacy and Consent Declaration" on this form, and I agree to its terms and conditions.

Prescriber Information

Physician Stamp

First name: _____

Last name: _____

Medical license #: _____

Email address: _____

Telephone number: _____

Fax number: _____

Street address: _____

City: _____

Province: _____ Postal code: _____

Primary office contact person name (if different):

_____

Phone number: _____

Prescription Information

(to be completed **only** if using Programme pharmacy)

Patient name: _____

Date of birth: _____ DD/MM/YYYY

JINARC oral tablets:

◯ 45+15 mg (60 mg)
◯ 60+30 mg (90 mg)
◯ 90+30 mg (120 mg)

One ___ mg tablet p.o. AM and one ___ mg tablet 8 hours later

Disp: ___ weekly blister packs (14 tabs per pack)

Refill x ___

This original prescription constitutes a legal prescription for the patient for JINARC. The original copy of this prescription will be kept in my files and will not be re-used.

Signature: X _____

Date: _____ DD/MM/YYYY

Version 1

PRESCRIBER Privacy and Consent Declaration

The Programme is provided by Otsuka Canada Pharmaceutical Inc. ("Otsuka") and is administered by a designated third party service provider, McKesson Canada Corporation, a body corporate duly constituted under the laws of the province of Nova Scotia, having a place of business at 1 Concorde Gate, 4th Floor, Toronto, Ontario, M3C 3N6, acting on its behalf and for and on behalf of its Pharmaceutical Solutions Division, and McKesson Specialty Prescription Services Corporation, McKesson Specialty Prescription Services (B.C.) Corporation, and McKesson Specialty Prescription Services (Atlantic) Corporation (collectively referred to as "McKesson Canada"). Otsuka and McKesson Canada respect all applicable privacy laws and as such have agreed that identifiable patient information will not be given to Otsuka or any other third party unless required by law for safety information reporting. The Programme will limit data collection to information required for Programme administration. Generally accepted industry standards shall be used to store and protect confidential data, and access will be limited to staff and agents of the Programme who require access to perform their work for the purpose of Programme management. The Programme shall comply with and abide by all applicable privacy legislation in the jurisdictions in which the services for the Programme are to be provided and where the Programme information is stored. The Programme is only intended to provide support to your patients, to you (the Physician), and your treatment team so that you can best support patients that, in your professional judgement, would benefit from the Product. The Programme is also there to ensure that you and your team have the support and knowledge you need about the Product. The Programme is not intended to replace your professional judgement or the professional judgement of other healthcare professionals involved in the patient's care. As the physician prescribing the Product, you are responsible for using your professional judgement regarding the use of the Programme tools and services.

In accepting to participate in the Programme, I understand and agree:

(1) That I have received and reviewed the Product Monograph and I will undertake to use the Product as clinically appropriate for the purpose of the Programme.

(2) To provide cooperation and necessary information to facilitate all necessary steps for Patients to be able to seek private or public coverage and ensure that any such requests are submitted in a timely fashion or are underway prior to requesting the medication supplied by the Programme.

(3) To the collection, use and disclosure of information by the designated service provider, McKesson Canada, for the Programme to support its services and to meet Health Canada requirements for the Programme.

(4) To the disclosure by McKesson Canada to Otsuka that I have enrolled to participate in the Programme.

(5) To the disclosure by McKesson Canada to Otsuka of de-identified patient information, or as required, aggregated de-identified patient information (depending on the nature of the information) so as to not permit the identification of the patient, specifically: liver function test monitoring status, Product shipment history under the Programme, as well as high-level summary information including, but not limited to, size of Product patient population and those covered/non-covered by public or private plans.

(6) That email communication will not be used for the exchange of any patient personal information and/or health information.

(7) That the Programme may provide me with communications pertaining to the following: the Programme, the Product, other products from Otsuka, disease state information and other services that may be made available under the Programme. I may withdraw my consent from receiving future communications pertaining to the items above, at any time by contacting the Programme at the number provided.

(8) To the transfer of personal health information possibly outside of Canada and I understand that McKesson Canada will ensure adequate protections are in place to protect such information. However I understand that information processed, stored or transferred outside of Canada may be subject to different laws than Canada.

(9) That in the event that Otsuka appoints a third party service provider, other than McKesson Canada, I agree to the transfer of this PPAF and information contained herein, or related thereto, to such third party service provider under the same terms and conditions as set out herein.

I agree that, should I report safety information (including adverse events) and Product quality complaints to the Programme, I acknowledge that this information will be reported by McKesson Canada to Otsuka during the course of the patient's participation in the Programme. I also agree to be consulted to provide follow-up information, until such time as I explicitly inform Otsuka, in writing, of my desire not to be consulted. I acknowledge that such adverse event reports may need to be forwarded to regulatory authorities in and outside of Canada.

I hereby confirm that I have read and understood the information provided and related to the Programme, and agree to participate as a healthcare professional. I understand that I may suspend my participation in the Programme at any time. To do this, I must contact the Programme at the number provided. I further understand that the Programme is mandated by Health Canada and if I suspend my participation, access to the Product may be terminated. I further understand that Otsuka reserves the right in their sole discretion to modify, suspend access to, or terminate the Programme.

Patient-Prescriber Agreement Form (PPAF)

Please return this completed and signed PPAF by fax to: **1-844-3JINARC (354-6272).**

PATIENT FORM

PATIENT INITIALS	**As the PATIENT being prescribed JINARC, I acknowledge that:**
	I understand that JINARC slows the growth of the cysts in my kidneys which should help protect my kidneys from damage and failure.
	My Prescriber has given me a copy of the mandatory patient educational material about JINARC and has reviewed it with me.
	I understand the risks, especially for the liver, and the benefits that may occur over time when receiving treatment with JINARC, as presented by my Prescriber.
	I understand that I must go for blood tests to check my liver function during JINARC treatment, as prescribed by my Physician: monthly for the first 18 months, every 3 months for the next 12 months, and then every 3-6 months thereafter.
	I understand I should inform my Physician if I have symptoms like fatigue, loss of appetite, right upper abdominal discomfort, dark urine, or jaundice (yellowing of the eyes and skin).
	I understand that if I do not go for my blood tests, my pharmacy will no longer be able to order and dispense JINARC for me, which could lead to treatment discontinuations or interruptions.
	I should take this medicine every day exactly as my Physician has told me in order for JINARC to better protect my kidneys.
	I understand that my Physician may be invited to participate in a Canadian JINARC Patient Outcomes Registry to measure the impact of JINARC on my kidneys and overall health over time and that I may be invited to participate by signing a separate consent form. In the case that I agree to participate, I understand that the data collected from this Hepatic Safety Monitoring Programme will be transferred to the Registry, as appropriate.
	I have reviewed the "Patient Privacy and Consent Declaration" and I agree to its terms and conditions which allow my healthcare providers to share my health information, as defined in this document, to the Programme administrator, for the limited purpose of managing the JINARC Hepatic Safety Monitoring and Distribution Programme.

PATIENT INFORMATION

First name: _____ Last name: _____

Date of birth: _____DD/MM/YYYY_____ Gender: ◯ Male ◯ Female

Email address: _____

Mobile number: _____

Telephone number: _____

Street address: _____

City: _____ Province: _____ Postal code: _____

◯ I have read and agree to the Patient Privacy Statement and Consent Declaration on this form.

◯ By checking this box, I also agree to receive a "Welcome call" from the Programme nurse to confirm my enrollment in the Programme, my pharmacy of choice and to introduce me to the ORIJIN™ Patient Support Program which involves support to access reimbursement from my health insurance company, financial assistance (if and where required), access to a Programme nurse for counseling and other related services as they become available. All of which shall be subject to the same privacy consent granted on this form. I understand that McKesson Canada may need to disclose my Personal Information to my insurers and my healthcare providers in order to provide me with such services.

If you are unavailable, can the Programme leave you a message? ◯ Yes ◯ No

Best time for contact: ◯ Morning ◯ Afternoon ◯ Evening ◯ No preference

Signature: X _____ Date: _____DD/MM/YYYY_____

PHARMACY INFORMATION

Preferred pharmacy (Please select)

◯ Programme pharmacy*

● Patient's preferred pharmacy
(Provide contact information below)

Local pharmacy name:
MacDonald's Prescriptions, Renal Pharmacy

_____

Telephone number: _____

Street address:

_____

City: _____

Province: _____ Postal code: _____

*If the Programme pharmacy is selected as the patient pharmacy of choice, the prescriber must complete the Prescription Information section of the Prescriber Form.

Version 1

PATIENT Privacy and Consent Declaration

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I have been informed by my healthcare provider of the Hepatic Safety Monitoring & Distribution Programme ("Programme") purpose and have been given the opportunity to discuss this Programme with my healthcare provider. I understand that it is my right to refuse to sign this consent form. By signing the consent, I acknowledge my agreement to enroll in the Programme. I am aware that all McKesson Canada employees and their agents adhere to a strict privacy policy. I authorize my Physician and his/her staff, and my health insurer(s) to disclose my personal information, including information about my insurance, prescriptions, verifying or coordinating insurance coverage(s), medication delivery and compliance, medical condition and health ("Personal Information") to McKesson Canada for the purposes of the Programme and as otherwise permitted or required under law.

I also authorize my healthcare providers to provide McKesson Canada with this completed Patient-Prescriber Agreement Form on my behalf so that a Programme coordinator can contact me in connection with the Programme. I acknowledge that I am responsible for any charges by my cell phone provider, should I choose to be contacted on my cell phone for the purposes of the Programme. I authorize Otsuka to collect unidentifiable aggregate data for Programme management purposes. Non-identifying aggregate data may be used for publication during the Programme, however, my Personal Information will not be used or disclosed for any purpose other than as described above. All information collected will be archived by McKesson Canada. I understand that I have the right to revoke this consent at any time by contacting the Programme at 1-844-2JINARC (1-844-254-6272), however, information about me already collected and disclosed for the purposes of the Programme will not be destroyed, except under those exceptions specified by law. I may arrange a right of access to the information held by McKesson Canada, and may rectify deficient information. I acknowledge that revocation of consent may prevent my continued participation in the Programme. I further acknowledge that Otsuka reserves the right to terminate the Programme at any time without prior notice.

In the event that Otsuka appoints a third party service provider, other than McKesson Canada, I agree to the transfer of all my personal information, documentation and services to such third party service provider under the same terms and conditions as set out herein.

If an adverse event is disclosed by me and/or about my state of health through the Programme, such information will be conveyed to Otsuka, with my initials (and date of birth and/or gender, if known), so that Otsuka can follow up with my Physician appropriately. This is necessary for Otsuka to maintain the most up-to-date records as to the safety profile of its products. Adverse event information collected about me for the purposes of adverse event reporting may be viewed, stored and analyzed outside of Canada. Otsuka and/or its agents will abide by the local applicable privacy laws in the country in which the data is stored. Adverse event information may also need to be reported to health authorities in and outside of Canada, where it may be subject to the laws of foreign jurisdictions.

Since JINARC can only be sold to pharmacies by a unique distributor (McKesson Canada), I authorize the Programme to contact my pharmacy of choice (indicated on this form or that I will have communicated to the Programme) to provide the pharmacy with the instructions and requirements to order JINARC. I understand that the information shared between my pharmacy and the Programme will only pertain to my treatment with JINARC and participation in the Programme.

I understand that Otsuka reserves the right to terminate the Programme, or any aspect thereof, at any time, in its sole discretion, without prior notice.