LUPIN GENESIS
PATIENT SUPPORT PROGRAM

PrLUPIN-TOLVAPTAN Consolidated Patient-Prescriber Agreement Form (PPAF) Enrollment Form

Once the consolidated PPAF enrollment form is completed and signed, please return via fax to: 1-866-488-1457

Prescriber Section

Patient ID number:

To be provided by the PSP provider

LUPIN-TOLVAPTAN (tolvaptan) is available in Canada and **can only be prescribed to patients who have completed and signed this form with their prescriber**.

The purpose of this consolidated Patient-Prescriber Agreement Form (PPAF) enrollment form is to document the fully considered engagement of both the patient and prescriber for the treatment of autosomal dominant polycystic kidney disease (ADPKD) with LUPIN-TOLVAPTAN ("Product").

The manufacturer of LUPIN-TOLVAPTAN is Lupin Pharma Canada Ltd. ("Lupin"). Lupin will implement a Lupin Genesis program. Lupin will be responsible for this Lupin Genesis program and may administer, in whole or in part, with a designated third-party service provider(s).

LUPIN-TOLVAPTAN is indicated to slow the progression of kidney enlargement and kidney function decline in patients with ADPKD. In ADPKD, kidney enlargement reflects renal cyst burden.

The prescriber and patient should discuss about the appropriate use of LUPIN-TOLVAPTAN before initiation of treatment, considering the potential benefits and risks of treatment, appropriate patient selection, and the need for mandatory ongoing hepatic function monitoring.

Once mutually agreed to undertake treatment with LUPIN-TOLVAPTAN, both the patient and their prescriber must complete, sign, and date this consolidated PPAF enrollment form in person, together at the same time for treatment-naive patients. For patients that are already treated with active ingredient tolvaptan, both the patient and their prescriber must complete, sign, and date this consolidated PPAF enrollment form. The patient and prescriber must read each statement of their respective section(s) of this consolidated PPAF enrollment form thoroughly and attest to his/her understanding of the benefits and risks of treatment with LUPIN-TOLVAPTAN and agree to comply with the conditions for safe use prior to initiating LUPIN-TOLVAPTAN.

Once the consolidated PPAF enrollment form is completed and signed, please return via fax to: 1-866-488-1457. If you have any questions regarding the Lupin Genesis program, please call 1-866-488-6017. If consent is provided by the patient, a program coordinator and/or designee will contact the patient to acknowledge and confirm enrollment. LUPIN-TOLVAPTAN is only distributed to pharmacies through distributor/s who will verify with the Lupin Genesis program if a signed and valid consolidated PPAF enrollment form is on file prior to distributing LUPIN-TOLVAPTAN. **To allow the Lupin Genesis program patient's designated pharmacy to dispense LUPIN-TOLVAPTAN, the prescriber should complete the prescription information section on this form.** Both the patient and prescriber should keep a copy of the executed signed consolidated PPAF enrollment form for their records.

The consolidated PPAF enrollment form will have to be renewed if there is any change to the patient's prescriber. In case there are significant changes to the Lupin Genesis program, this consolidated PPAF enrollment form or the Product Monograph for LUPIN-TOLVAPTAN, the prescriber and the patient will be contacted and informed of such changes. The consolidated PPAF enrollment form is specific to LUPIN-TOLVAPTAN and cannot be used for any other product.

PRESCRIBER INITIALS	As the PRESCRIBER of LUPIN-TOLVAPTAN for the undersigned patient, I acknowledge and confirm that:
	☐ I am a nephrologist, or ☐ I am a specialist experienced in the management of ADPKD. Please provide a brief description of your experience/training:
	I understand that LUPIN-TOLVAPTAN is indicated to slow the progression of kidney enlargement and kidney function decline in patients with ADPKD. In ADPKD, kidney enlargement reflects renal cyst burden.
	I understand that LUPIN-TOLVAPTAN is contraindicated in patients: who have been asked to permanently discontinue tolvaptan in the past; with known or suspected hypersensitivity to tolvaptan, benzazepine or benzazepine derivatives (e.g., mirtazapine) or any of the excipients; with hypovolemia; with hypernatremia; with anuria; who do not have access to fluids or who cannot respond to the physiologic sensation of thirst; with a history, signs or symptoms of significant liver impairment or injury, excluding uncomplicated polycystic liver disease; who are using strong CYP3A inhibitors; who are pregnant or nursing; or who have one of the following rare hereditary diseases: Galactose intolerance, Lapp lactase deficiency or Glucose-galactose malabsorption.
	I understand that LUPIN-TOLVAPTAN 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 at, or approaching, end-stage renal disease, would not be expected to benefit from LUPIN-TOLVAPTAN treatment.
	I understand that the patients most likely to benefit from LUPIN-TOLVAPTAN treatment according to the TEMPO 3:4 trial, 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. Patients who are also likely to benefit from LUPIN-TOLVAPTAN according to the REPRISE trial, appear to be those at high risk of progressive eGFR decline based on renal function for age (18 to 65 years of age with baseline eGFR between 25 and 65 mL/min/1.73 m^2). I will comply with patient selection criteria as outlined in the totality of the LUPIN-TOLVAPTAN Product Monograph.
	I have reviewed and understood the risks and potential benefits of LUPIN-TOLVAPTAN, as well as the requirements of the Lupin Genesis program.
	I have counselled my patient about the potential risks and benefits of LUPIN-TOLVAPTAN, the parameters for selection for him/her for this treatment, the appropriate use of LUPIN-TOLVAPTAN, as well as the need for mandatory ongoing hepatic function testing.
	I have provided and reviewed the mandatory LUPIN-TOLVAPTAN patient educational material with my patient.
	I understand the Lupin Genesis program 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 Lupin Genesis program in order to ensure that the patient's pharmacy can continue to order and dispense LUPIN-TOLVAPTAN to my patient. I acknowledge that failure to do so may lead to LUPIN-TOLVAPTAN treatment interruptions for this patient. I understand the program coordinator may contact me after sending the liver function status report form to follow up on the availability of pending results or to provide me with information on the Lupin Genesis program.
	Prior to initiating and prescribing LUPIN-TOLVAPTAN, 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

Prescriber 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):

_____

Contact number: _____

Prescription Information

Patient's first name: _____

Patient's last name: _____

LUPIN-TOLVAPTAN 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 LUPIN-TOLVAPTAN. The original copy of this prescription will be kept in my file and will not be re-used. Completion of this section is required for medication to be dispensed.

Signature: X _____

Date: (DD/MM/YYYY) _____

Privacy and Consent Declaration

The Lupin Genesis program is provided by Lupin Pharma Canada Ltd. ("Lupin") and may be administered, in whole or in part, by Lupin and/or a designated third-party service provider(s).

Lupin, and/or any other designated third-party service provider(s) for the Lupin Genesis program, shall comply with and abide by all applicable privacy legislation in the jurisdictions in which the services for the Lupin Genesis program are to be provided and where the Lupin Genesis program information is stored. The Lupin Genesis program is only intended to provide support to your patients, to you (the Prescriber), and your treatment team so that you can best support patients that, in your professional judgement, would benefit from LUPIN-TOLVAPTAN. The Lupin Genesis program will ensure that you and your team have the support and knowledge needed about LUPIN-TOLVAPTAN.

Lupin and/or any other designated third-party service provider(s) for the Lupin Genesis program will limit the collection, through this form, of personal patient information ("Personal Information") only to information that is required for Lupin Genesis program administration. Such personal patient information will only be accessible to employees of Lupin and/or any other designated third-party service provider(s) for the Lupin Genesis program directly involved in the provision of the services and support to the Lupin Genesis program and by any other third party if required by law or for safety information reporting unless specific consent has been obtained. The personal patient information is stored on our servers and/or by designated third-party service provider(s) for the Lupin Genesis program, located in Canada, and physical, organizational, contractual and technological security measures have been implemented to protect it. Personal patient information will be used, disclosed or retained only as long as necessary for the fulfilment of those purposes and to the extent permitted or required by law.

PATIENTS HAVE THE RIGHT TO ACCESS AND RECTIFY THEIR PERSONAL INFORMATION AND MAY WITHDRAW THEIR CONSENT AT ANY TIME.
For further information, our Privacy Officer can be contacted at the following address:

Mail: Attn: Compliance & Ethics Office Americas and EMEA
Lupin Pharma Canada
1111, St-Charles Street West, Suite 550
Longueuil, Quebec J4K 5G4

Email: complianceandethicsoffice@lupin.com

The Lupin Genesis program is not intended to replace your professional judgement, or the professional judgement of other healthcare professionals involved in the patient's care. As the Prescriber of LUPIN-TOLVAPTAN, you are responsible for using your professional judgement regarding the use of the Lupin Genesis program tools and services.

By participating in the Lupin Genesis program, as the Prescriber of LUPIN-TOLVAPTAN for the undersigned patient, I understand and agree:

(1) That I have received and reviewed the Product Monograph and I will undertake to use LUPIN-TOLVAPTAN as clinically appropriate for the purpose of the Lupin Genesis program.

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

(3) To the collection, use and disclosure of information by the program coordinator and/or designee for the Lupin Genesis program to support its services and to meet Health Canada requirements for the Lupin Genesis program.

(4) To the disclosure by the program coordinator and/or designee to Lupin personnel that I have voluntarily enrolled to participate in the Lupin Genesis program.

(5) To the disclosure by the program coordinator and/or designee to Lupin personnel, not part of the Lupin Genesis program Support Team, 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 Lupin Genesis program, 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 patient personal information and/or health information and/or adverse events may be collected, viewed, stored and analyzed in or outside of Canada where we have facilities or in which we use third-party service providers. In that case, Personal Information will be subject to the laws of the country in which they are located and may be disclosed to governments, courts or law enforcement or regulatory agencies of that other country and in accordance with the laws of that other country, but the practices of the program coordinator and/or designee regarding my personal information will at all times be governed by the Lupin Genesis program privacy policy.

(8) If I report safety information including adverse events and product quality complaints to the Lupin Genesis program, I acknowledge that this information will be reported by the program coordinator and/or designee to Lupin during the course of the patient's participation in the Lupin Genesis program. Upon providing consent to provide follow-up information, Lupin can contact me, until I explicitly inform Lupin, 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.

(9) In the event that Lupin appoints a third-party service provider, for the administration of the Lupin Genesis program, in its entirety or for a specific service for or through the Lupin Genesis program, I agree to the transfer of this consolidated PPAF enrollment form and information contained herein, or related thereto, to such third-party service provider under the same terms and conditions as set out herein.

(10) That this consolidated PPAF enrollment form is only applicable for treatment with LUPIN-TOLVAPTAN.

I hereby confirm that I have read and understood the information provided and related to the Lupin Genesis program and agree to participate as a Prescriber.

I understand that I may suspend my participation in the Lupin Genesis program at any time. To do this, I must contact the program coordinator and/or designee at the number provided. I further understand that the Lupin Genesis program is mandated by Health Canada and if I suspend my participation, access to the Product may be terminated. I further understand that Lupin reserves the right in their sole discretion to modify, suspend access to, or terminate the Lupin Genesis program.

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Patient Section

Patient ID number:

To be provided by the PSP provider

PATIENT INITIALS	As the PATIENT being prescribed LUPIN-TOLVAPTAN, I acknowledge that:
	I understand that LUPIN-TOLVAPTAN is able to slow the growth of cysts in kidneys and the decline of kidney function. This should help protect my kidneys from damage and failure.
	My Prescriber has reviewed the mandatory patient educational material about LUPIN-TOLVAPTAN and has given a copy to me.
	I understand the benefits and risks when receiving treatment with LUPIN-TOLVAPTAN, as presented by my Prescriber.
	I understand that I must go for blood tests to check my liver function during LUPIN-TOLVAPTAN treatment, as prescribed by my Prescriber: monthly for the first 18 months, every 3 months for the next 12 months, and then every 3-6 months thereafter.
	I understand that if I do not go for my blood tests, the pharmacy will no longer be able to order and dispense LUPIN-TOLVAPTAN for me, which could lead to treatment discontinuations or interruptions.
	I understand I should inform my Prescriber if I have symptoms like fatigue, loss of appetite, right upper abdominal discomfort, dark urine, or jaundice (yellowing of the eyes and skin).
	I should take this medicine every day exactly as my Prescriber has told me in order for LUPIN-TOLVAPTAN to better protect my kidneys.
	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 program coordinator, for the purpose of managing the Lupin Genesis program.

For patients that are already treated with active ingredient tolvaptan only:

PATIENT INITIALS	As the PATIENT being prescribed LUPIN-TOLVAPTAN, I acknowledge that:
	I have previously discussed with my Prescriber in person, together at the same time the appropriate use of tolvaptan before initiation of treatment, considering the potential benefits and risks of treatment, appropriate patient selection, and the need for mandatory ongoing hepatic function monitoring.
	I have previously read with my Prescriber in person, together at the same time each statement of the PPAF thoroughly, added my initials before each of them confirming that I understand the benefits and risk of treatment with tolvaptan, and agreed to comply with the conditions for use prior to initiating tolvaptan.
	I confirm and attest that I had no interruption in blood tests to check my liver function during tolvaptan treatment, as prescribed by my Prescriber: monthly for the first 18 months, every 3 months for the next 12 months, and then every 3-6 months thereafter.

Patient Information

Referred by: ☐ Nephrologist ☐ Family physician

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: _____

Name of your family physician:* _____

Telephone number: _____ Fax number: _____

Street address: _____ City: _____ Province: _____ Postal code: _____

Name of your pharmacist:* _____

Telephone number: _____ Fax number: _____

Street address: _____ City: _____ Province: _____ Postal code: _____

* By providing us with the names of your family physician and your pharmacist, you are giving the Lupin Genesis program consent to inform them that you have been prescribed LUPIN-TOLVAPTAN and to provide them with information on autosomal dominant polycystic kidney disease and LUPIN-TOLVAPTAN.

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

☐ By checking this box, I also agree to receive a "welcome call" from the program coordinator to confirm my enrollment in the Lupin Genesis program, the pharmacy and to introduce me to the LUPIN-TOLVAPTAN access to a program coordinator for counselling 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 the program coordinator and/or designee may need to disclose my Personal Information to my insurers and my healthcare providers in order to provide me with such services.

☐ By checking this box, I agree to share my email address and first name with Lupin, the makers of LUPIN-TOLVAPTAN, for the purpose of receiving the LUPIN-TOLVAPTAN Newsletter and other electronic communications from www.LupinGenesis.com. I will have the opportunity to opt out from such communications.

If you are unavailable, may the program coordinator and/or designee leave you a message? ☐ Yes ☐ No

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

Signature: X Date: (DD/MM/YYYY)

Privacy and Consent Declaration

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I have been informed by my healthcare provider of the Lupin Genesis program purpose and have been given the opportunity to discuss this Lupin Genesis program 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 LUPIN GENESIS PROGRAM.

I AUTHORIZE MY PRESCRIBER 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 THE LUPIN GENESIS PROGRAM SUPPORT TEAM FOR THE PURPOSES OF THE LUPIN GENESIS PROGRAM AND AS OTHERWISE PERMITTED OR REQUIRED UNDER LAW. I AM AWARE THE LUPIN GENESIS PROGRAM SUPPORT TEAM ADHERES TO A STRICT PRIVACY POLICY.

I understand that my Personal Information will be retained only as long as necessary for the fulfilment of the purposes for which it was collected and/or for which consent was received, unless otherwise required by law. My Personal Information that is no longer required to fulfil the identified purposes will be destroyed, erased or made anonymous.

I also authorize my healthcare provider to provide the program coordinator and/or designee with this completed consolidated Patient-Prescriber Agreement Form ("PPAF") enrollment form on my behalf so that the Lupin Genesis program Support Team can contact me in connection with the Lupin Genesis program. I acknowledge that I am responsible for any charges by my cell phone provider, should I choose to be contacted on my cell phone.

I authorize Lupin personnel, not part of the Lupin Genesis program Support Team, to collect unidentifiable aggregate data for Lupin Genesis program management purposes. Unidentifiable aggregate data may be used for publication relating to the Lupin Genesis program; 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 the program coordinator and/or designee. If an adverse event is disclosed by me and/or about my state of health through the Lupin Genesis program, such information will be conveyed to Lupin with my initials (and date of birth and/or gender, if known), so that Lupin can follow up with my Prescriber appropriately. This is necessary for Lupin to maintain the most up-to-date records as to the safety profile of its products.

I consent to my Personal Information and any information relating to adverse events reporting being collected, viewed, stored and analyzed in or outside of Quebec and Canada where Lupin has facilities or in which third-party service providers are used. In that case, my Personal Information will be subject to the laws of the country in which they are located and may be disclosed to governments, courts or law enforcement or regulatory agencies of that other country and in accordance with the laws of that other country, but the practices of the program coordinator and/or designee regarding my Personal Information will at all times be governed by the Lupin Genesis program privacy policy.

I UNDERSTAND THAT I HAVE THE RIGHT TO REVOKE THIS CONSENT AT ANY TIME BY CONTACTING THE LUPIN GENESIS PROGRAM AT 1-866-488-6017; HOWEVER, INFORMATION ABOUT ME ALREADY COLLECTED AND DISCLOSED FOR THE PURPOSES OF THE LUPIN GENESIS PROGRAM WILL NOT BE DESTROYED, EXCEPT UNDER THOSE EXCEPTIONS SPECIFIED BY LAW. I MAY ARRANGE A RIGHT OF ACCESS TO THE INFORMATION HELD BY THE PROGRAM COORDINATOR AND/OR DESIGNEE AND MAY RECTIFY DEFICIENT INFORMATION. I ACKNOWLEDGE THAT REVOCATION OF CONSENT MAY PREVENT MY CONTINUED PARTICIPATION IN THE LUPIN GENESIS PROGRAM.

Since LUPIN-TOLVAPTAN can only be sold to the patient's designated pharmacy, I authorize the Lupin Genesis program to contact if needed my pharmacy (indicated on this form or that I will have communicated to the Lupin Genesis program) to provide instructions and requirements to my pharmacy to order LUPIN-TOLVAPTAN.

I understand that the information shared between my pharmacy and the Lupin Genesis program will only pertain to my treatment with LUPIN-TOLVAPTAN and participation in the Lupin Genesis program.

I understand that this consolidated PPAF enrollment form is not applicable for any treatment other than LUPIN-TOLVAPTAN and that Lupin reserves the right to terminate the Lupin Genesis program, or any aspect thereof, at any time, in its sole discretion, without prior notice.