Tolvaptan for ADPKD Shared System REMS | PATIENT ENROLLMENT FORM

Tolvaptan for Autosomal Dominant Polycystic Kidney Disease (ADPKD) is available only through the Tolvaptan for ADPKD Shared System REMS, a restricted distribution program. Only prescribers, pharmacies, and patients enrolled in the Tolvaptan for ADPKD Shared System REMS can prescribe, dispense, and receive tolvaptan for ADPKD. Your certified healthcare provider will help you complete this form and provide you with a copy.

Prescribers and Patients: Please complete this form online at www.TolvaptanADPKDSharedREMS.com or once completed, fax it to the REMS at 1-866-750-6820.

**Indicates required field*

Patient Information

First Name*: _____ Middle Initial: _____ Last Name*: _____

Date of Birth (MM/DD/YYYY)*: _____ Sex*: ☐ Male ☐ Female

Race*: ☐ White ☐ Black or African American ☐ American Indian or Alaska Native

☐ Asian ☐ Native Hawaiian or Other Pacific Islander ☐ Other, Specify _____

Ethnicity*: ☐ Hispanic or Latino ☐ Not Hispanic or Latino

Address Line 1*: _____

Address Line 2: _____

City*: _____ State*: _____ Zip code*: _____

Phone*: _____ Mobile Phone*: _____ Email*: _____

Prescriber Information

First Name*: _____ Last Name*: _____

National Provider Identifier No. (NPI)*: _____

Practice/Facility Name (where you see this patient): _____

Address Line 1: _____

City: _____ State: _____ Zip code: _____

Phone*: _____ Fax: _____ Email: _____

Prescriber Agreement

*Has the patient's liver function been assessed by evaluating ALT, AST, and bilirubin prior to enrolling this patient in the REMS?

☐ Yes ☐ No

If the answer is No, you must assess the patient's liver function by evaluating ALT, AST, and bilirubin prior to submitting this form to the REMS.

By signing below, I acknowledge that I have reviewed and discussed the risks of tolvaptan for ADPKD and the requirements of the Tolvaptan for ADPKD Shared System REMS with this patient.

Prescriber Signature*: _____ Date*: _____

Healthcare Provider: Provide a copy of this form to the patient.

PATIENT ENROLLMENT FORM

Patient Agreement

Before my treatment begins, I will:

- Review the **Patient Guide**.
- Enroll in the REMS by completing the **Patient Enrollment Form** with my healthcare provider. Enrollment information will be provided to the REMS.
- Get a blood test to check my liver.
- Receive counseling from my healthcare provider on the risk of serious liver problems and possibly death and requirements to get blood tests by using the **Patient Guide**.

During treatment, I will get a blood test to check my liver:

- 2 weeks after my treatment begins,
- 4 weeks after treatment begins, and then
- every month after that for the first 18 months, and then
- every 3 months

I will contact my healthcare provider if I have any side effects, reactions, or symptoms after receiving tolvaptan for ADPKD

I understand and acknowledge that:

1. I have received, read, and understand the **Patient Guide** that my healthcare provider has given me.
2. Tolvaptan for ADPKD can cause serious side effects. It can cause serious liver problems and possibly death. This complication can be identified through monthly testing and awareness of side effects, reactions, or symptoms. My healthcare provider has reviewed with me the risks of treatment with tolvaptan for ADPKD.
3. In order to receive tolvaptan for ADPKD, I am required to be enrolled in the Tolvaptan for ADPKD Shared System REMS, and my information will be stored in a database of all patients who receive tolvaptan for ADPKD in the United States.
4. I should tell the REMS right away if I change my tolvaptan for ADPKD healthcare provider, if my contact information changes, or if I discontinue tolvaptan for ADPKD.
5. The Tolvaptan for ADPKD Applicants and their agents may contact me via phone, mail, fax, or email to support administration of the REMS.
6. My protected health information will be stored in a secure and confidential database.
7. The Tolvaptan for ADPKD Applicants and their agents may use and share my personal health information, including lab results and prescription data collected as part of the REMS for the purpose of the operations, analysis, and reporting of the REMS including enrolling me into, administering, and evaluating the REMS, coordinating the dispense of tolvaptan for ADPKD, and releasing my personal health information to the Food and Drug Administration (FDA), as necessary.

Patient or Legal Guardian Signature*: _____

Date*: _____

Printed Patient/Legal Guardian Name: _____

Healthcare Provider: Provide a copy of this form to the patient.