

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.

Instructions:

- 1) **Review** the Prescribing Information, the **Program Overview**, and the **Prescriber Training**.
- 2) **Complete** and **submit** the **Prescriber Knowledge Assessment** and this **Prescriber Enrollment Form** online at www.TolvaptanADPKDSharedREMS.com, or fax them to the REMS at **1-866-750-6820**.
- 3) **Complete** all mandatory fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS will notify you upon successful certification.

**Indicates required field*

Prescriber Information

First Name*: _____ Middle Initial: _____ Last Name*: _____
National Provider Identifier No. (NPI)*: _____ State License No: _____
Preferred Method of Contact: Phone Email Fax Preferred time of contact: AM PM
Credentials*: MD DO NP PA Other Specialty*: Nephrology Other: _____
Practice/Facility Name: _____
Address Line 1*: _____
Address Line 2: _____
City*: _____ State*: _____ Zip code*: _____
Phone*: _____ Fax*: _____ Email*: _____
Office Liaison First Name: _____ Office Liaison Last Name: _____
Office Liaison Email: _____

Prescriber Agreement

By signing this form, I agree tolvaptan for ADPKD is only available through the REMS and I must comply with the following REMS requirements:

I have:

1. Reviewed the Prescribing Information.
2. Reviewed the **Program Overview**.
3. Completed the **Prescriber Training**.
4. Successfully completed the **Prescriber Knowledge Assessment** and submitted it to the REMS.

Before treatment initiation with the first dose I must:

1. Counsel the patient on the risk of serious and potentially fatal liver injury and the requirement for liver function monitoring at baseline, 2 weeks and 4 weeks after treatment initiation, then monthly for the first 18 months and then every 3 months thereafter using the **Patient Guide**.
2. Provide a copy of the **Patient Guide** to the patient.
3. Assess the patient's liver function and appropriateness of initiating treatment.
4. Document appropriateness of initiating treatment using the **Patient Enrollment Form**.
5. Enroll the patient by completing and submitting the **Patient Enrollment Form** to the REMS. Provide a copy of the form to the patient.

During treatment, at 2 weeks and 4 weeks after treatment initiation, then monthly for the first 18 months and every 3 months thereafter I must assess the patient's liver function and appropriateness of continuing treatment.

Prescriber Agreement (continued)

During treatment, every 3 months for the first 18 months and every 6 months thereafter I must:

1. Assess the patient's liver function and appropriateness of continuing treatment.
2. Document appropriateness of continuing treatment and submit to the REMS using the **Patient Status Form**.

At all times, I must:

1. Report adverse events suggestive of serious and potentially fatal liver injury by contacting the REMS by phone or using the **Patient Status Form**.
2. Report treatment discontinuation or transfer of care to the REMS.

I understand and acknowledge that:

1. I will only be able to prescribe tolvaptan for ADPKD if certified in the Tolvaptan for ADPKD Shared System REMS.
2. I will not share my credentials for the **REMS Website** or allow others to sign into the website using my credentials.
3. I will allow the Tolvaptan for ADPKD Applicants and their agents to contact me via phone, mail, fax, or email to support administration of the REMS.
4. I will be contacted for further information regarding any reports of serious and potentially fatal liver injury and will be requested to provide pertinent laboratory test results.

Prescriber Signature*: _____ Date*: _____